

1

Tuesday, 10 May 2011

2 (9.30 am)

3 (Proceedings delayed)

4 (9.54 am)

5 THE CHAIRMAN: Good morning.

6 MS DUNLOP: Good morning, sir. We are sorry for the delay  
7 but we have been printing out Dr Foster's paper so that  
8 people will be able to follow it in hard copy as well as  
9 on the screen, and that has taken slightly longer than  
10 anticipated.

11 DR PETER FOSTER (sworn)

12 Questions by MS DUNLOP

13 MS DUNLOP: Dr Foster, good morning. We generally begin by  
14 looking at a witness' curriculum vitae and I would like  
15 to do that with you, if I may. We have it in our system  
16 and its number is WIT0030389.

17 On the first page you have narrated your education.  
18 We can see your school education and that you studied at  
19 Heriot-Watt. You took a first-class honours degree in  
20 chemical engineering in 1968 and then you proceeded to  
21 University College London, where you did a PhD. We can  
22 see the subject matter of that almost in the middle of  
23 the page.

24 Your membership of professional bodies reveals that  
25 you are a clinical scientist, regulated, I take that to

1 mean, by the Health Professions Council?

2 A. That's correct.

3 Q. And you are a chartered scientist under the Science  
4 Council. What's the difference between those two?

5 A. The Science Council is more like the Engineering Council  
6 and it's a relatively recent development of the  
7 engineering Council to accommodate science as well as  
8 engineering. So my membership of that is really through  
9 the Institute of Chemical Engineers.

10 Q. Right. And does it have any regulatory function?

11 A. No, it doesn't. It is a professional body.

12 Q. If we look on to the following page, please, we can see  
13 your appointments listed. Really your whole working  
14 life was spent within the Scottish National Blood  
15 Transfusion Service. Is that correct?

16 A. That's correct.

17 Q. Yes. You started as a research scientist in 1973 and  
18 you became the head of research and development, and  
19 although your grading or the name of your grade seems to  
20 have changed, that was the position you occupied until  
21 you became development manager in 1991. Is that right?

22 A. That's correct, even then it was essentially the same  
23 job, just a revision of the titles.

24 Q. Right. You have management experience and we note from  
25 that section that -- this is about half way down -- you

1 were a member of the PFC, Protein Fractionation Centre  
2 management team between 1974 and 2008. You tell us --  
3 and I'm reading up the way now, two bullets above  
4 that -- that you were responsible for maintaining  
5 awareness of scientific knowledge and protecting  
6 intellectual property. So not just your own awareness  
7 of scientific knowledge but a certain amount of  
8 dissemination as well?

9 A. That's correct. We had a library and I tended to take  
10 responsibility for that at the time.

11 Q. I notice that too, that you were responsible for the  
12 library, so you were responsible for planning and  
13 managing the PFC library, which must have been a useful  
14 way for you personally to notice recent developments?

15 A. Obviously one has to keep up with the field. So that  
16 was a good way to do it.

17 Q. You were responsible for line management and financial  
18 management of PFC development department between 1974  
19 and 2008. You had responsibility, reading from the  
20 first bullet, for planning, managing and reviewing PFC  
21 product and process developments and contract research  
22 and development activities from 1974 to 2008.

23 The section headed "Scientific contributions"  
24 reveals that, among many, between 1973 and 1975 -- and  
25 I need to go to the next page because I'm starting again

1 at the furthest point in time -- responsible for  
2 development of automated continuous flow technology for  
3 cold ethanol fractionation of plasma. Leader of SNBTS  
4 team concerned with increasing the Factor VIII content  
5 of plasma supply to PFC. Developing methods and  
6 technology to increase Factor VIII yield and process  
7 capacity, enabling Scotland to achieve self-sufficiency  
8 in Factor VIII supply, 1981 to 1986. Developing  
9 a method for stabilising Factor VIII, now used by all  
10 major manufacturers to enable virus inactivation;  
11 further purification to be carried out without an  
12 unacceptable loss of yield. Developed a method for  
13 precipitating fibrinogen from Factor VIII solutions.

14 Then back to the previous page, please:

15 "1981 to 1986, development of heat treatment methods  
16 for inactivating HIV and hepatitis in Factor VIII and  
17 Factor IX."

18 Then again reading up, 1990 to 1994, I noticed,  
19 project manager for the development of high purity  
20 Factor VIII, which is Liberate. Many of these things  
21 crop up in the paper which you have prepared and in  
22 which we are going to look in more detail, but certainly  
23 we recognise a number of themes in that list.

24 Going to page 3 again, please, we see that today's  
25 is by no means your first experience of giving evidence

1 in this area. Looking at around the middle, you were  
2 a witness to the independent public inquiry under  
3 Lord Archer. You were the author of SNBTS evidence  
4 submitted to investigations by the Scottish executive  
5 and the Scottish Parliament. Author of papers for the  
6 SNBTS concerning evidence to the Scottish public inquiry  
7 under Lord Penrose. Invited expert witness to the  
8 tribunal of Inquiry in Ireland, the Lindsay Tribunal.  
9 Witness in USA, multi-district litigation.

10 Then towards the bottom, some more regular  
11 scientific activity: as a PhD supervisor and external  
12 examiner, and then of course at the very top, your  
13 invited reviews, scientific papers, 70 letters and  
14 abstracts and eight patent applications. Speaker at  
15 many conferences or symposia and lectures and seminars.  
16 The next page lists the patent applications. Successful  
17 patent applications?

18 A. Successful in that, I think, most of them were granted.  
19 I wouldn't say they made any money. Certainly I never  
20 saw any.

21 Q. Intellectually successful but not perhaps --

22 A. That's a good way to put it.

23 Q. -- but not enriching financially.

24 THE CHAIRMAN: Did they all stand the test of time or were  
25 there revocations?

1 A. I think some of them have stood the test of time and  
2 some have not.

3 MS DUNLOP: Then you have a long list of publications,  
4 Dr Foster, entirely as one would expect. I'm not going  
5 to take you through them. I wonder if it's fair to say  
6 that in general they relate to processing matters;  
7 things like yield, to heat treatment, to viral  
8 inactivation and then gradually as we read through them  
9 chronologically, we see VCJD appearing and some work on  
10 prions, and also from time to time the history of how  
11 these matters have developed, particularly in Scotland.  
12 Have I left anything out?

13 A. No, that's a reasonable summary, yes.

14 Q. Right, thank you.

15 One that struck me, if we just look at the third  
16 page of these, number 28, it was just the use of  
17 a different term from the term "self-sufficiency", I saw  
18 the term "self-reliance" being used there, which perhaps  
19 is an interesting alternative description of what at  
20 least I understand people to have been trying to  
21 achieve.

22 A. Yes, that was the term that the Swedish government or  
23 the Swedish authorities used when Dr Perry was invited  
24 to give that presentation. So that was the terminology  
25 that they applied.

1 Q. Were they the only ones who liked "self-reliance" as  
2 a term?

3 A. It's the only time I have come across it, I think.

4 Q. Right. 34 is an example of the phenomenon I alluded to  
5 of documenting the history of matters. "Plasma  
6 fractionation in Scotland: the first 30 years".

7 Then going on, we can see 66 is a contribution to  
8 a book, "Blood, blood products and HIV." some of these  
9 book titles, Dr Foster, I recognise because we have them  
10 on our shelves. We have quite a library of our own,  
11 which might not surprise you.

12 I noticed, if we go on to number 122, that you had  
13 also written an obituary of John Watt. When did Mr Watt  
14 die?

15 A. That was last year.

16 Q. It was last year. Then your presentations are listed as  
17 well. Constant outflow of academic work as well as,  
18 presumably, your day job?

19 A. I'm not sure I would call it "academic". You do get  
20 invited to talk to students from time to time.

21 Q. Actually I was going to ask you that as well. Have you  
22 done much teaching?

23 A. Just a little bit and it's listed here in these  
24 presentations.

25 Q. I'm comforted by that because you may have to do some

1           today. We are all obviously coming at this as  
2           non-scientists essentially. Although I don't want to  
3           demean anybody who might have a first degree in science,  
4           but I suppose, speaking for myself, starting from a low  
5           knowledge base, so, as I think we have said, please feel  
6           free to explain things in basic terms as the questions  
7           demand.

8           You have prepared for us both a witness statement  
9           and a separate paper, Dr Foster. The witness statement  
10          is [\[PEN0150101\]](#). You explain the structure of your  
11          response. You were sent a standard schedule, which was  
12          prepared by the Inquiry team last summer and you  
13          responded to that. But probably more importantly, if we  
14          go on to the second page, we can see that you took up  
15          the invitation to provide any additional information you  
16          thought was relevant and you did so by preparing  
17          a paper, which is entitled "Self-sufficiency and the  
18          supply of blood products in Scotland, with particular  
19          reference to the treatment of Haemophilia A."

20          You say what's included in your paper and if we go  
21          on to the following page, please, you say:

22          "Although the preliminary report addresses this  
23          topic there is material in my paper which has not been  
24          included in the preliminary report and which may be of  
25          assistance to the Inquiry."



1           Dr Foster, I don't think there is any doubt of that  
2           and because of that, it's my intention, sir, just to go  
3           at this point to Dr Foster's paper and spend some time  
4           looking at that.

5   THE CHAIRMAN: Well, Dr Foster, I think I would have been  
6           surprised if there hadn't been omissions from the  
7           preliminary report given that it was a paper exercise  
8           and depended largely on what we could find, but I badly  
9           need to have your input so that I can understand the way  
10          things did develop. So please do make sure that we get  
11          the proper and full story.

12   A. Okay. I must say the preliminary report was very  
13          excellent. So I think it was really quite impressive.

14   THE CHAIRMAN: I know that there are large gaps in it, not  
15          least that it was published before I had taken on board  
16          fully the 1972 joint symposium of The Royal College here  
17          in Edinburgh and the College of Physicians, which set  
18          a sort of position at 1972, which is not properly  
19          reflected at all. But there will be a lot that you can  
20          fill in for us.

21   MS DUNLOP: Dr Foster, your paper is [\[PEN0131125\]](#) and  
22          I think you have a hard copy of it as well. You and  
23          Professor James should have hard copies in fact.

24                When you started in SNBTS in 1973, the name PFC,  
25          Protein Fractionation Centre, was already in use, as

1 I understand it? Is that right?

2 A. Yes, that name was adopted in 1970, and prior to that  
3 the unit had been called the Blood Products Unit, but  
4 there was some possibility of confusion with the Blood  
5 Products Laboratory at Elstree and it was decided to  
6 adopt a new name, and it was proposed that it should be  
7 called the Scottish Protein Fractionation Centre, and  
8 that took effect from 1 April 1970.

9 Q. Right. I should say you have dealt in your paper with  
10 the history of matters but that's quite a bit further on  
11 and it's certainly my intention to return to that and  
12 also to look at an article you have provided, which is  
13 a useful addition to our knowledge on the history of  
14 matters, but for the moment I think we really need to  
15 look more at the science.

16 So can we turn through your paper. You do provide,  
17 as is the custom nowadays, a sort of executive summary  
18 but we are going to bypass the executive summary because  
19 we are looking at the full text and if we can look at  
20 the introduction, which is page 10, please, so that's  
21 PEN0131134. You refer to previous consideration of  
22 self-sufficiency and to the opening of PFC. You say:

23 "Some 20 different plasma products were manufactured  
24 at PFC. Of these, Factor VIII concentrate presented the  
25 greatest challenge to the SNBTS, as it was the most

1           difficult product to manufacture and growth in demand  
2           was high."

3           Dr Foster, it is my understanding that Factor VIII  
4           is a very complex molecule. Is that correct?

5   A. It is quite a large molecule; that is correct. And  
6           because it co-purifies with other molecules that are  
7           also large and difficult to work with, the whole mixture  
8           that you are dealing with is really very difficult.  
9           I have to say, in all of my career, it is far and away  
10          the most difficult material I have ever had to work  
11          with.

12   Q. Perhaps you could explain what you mean by co-purify?

13   A. For example, you have heard a lot about cryoprecipitate,  
14          and that contains other proteins compared with  
15          Factor VIII. It contains predominantly fibrinogen and  
16          another protein called fibronectin. They have all, if  
17          you like, in that one step come together as a group. So  
18          if you regard cryoprecipitation as a purification step,  
19          then in that one step those proteins have all followed  
20          the same path, if you like, and kept together.

21   Q. Right. So there isn't any one physical step, as it  
22          were, that is an easy way to get Factor VIII on its own?

23   A. There isn't and perhaps it might help if I explain just  
24          how much Factor VIII we are dealing with. Because  
25          I think you have heard that it's actually a trace

1 component in plasma, and to put that into perspective,  
2 if you want to know what proportion of the protein in  
3 plasma Factor VIII represents, it's approximately 1 part  
4 in 150,000. That is like trying to find one person in a  
5 crowd of 150,000 people, which is about twice the size  
6 of Murrayfield stadium.

7 Q. So you have a big needle in a haystack problem.

8 A. That puts it very well, yes. So when one starts to try  
9 to find that needle, you get chunks of haystack as well.

10 Q. Right. Is it more complicated than Factor IX?

11 A. What do you mean by more complicated?

12 Q. Right. Is Factor IX a needle in a haystack or is the  
13 haystack smaller?

14 A. The haystack is smaller with Factor IX, so it is not so  
15 difficult, and Factor IX has properties that make it  
16 easier to find the needle, if I can put it that way.

17 Q. Just leaving that page, page 10, and moving on to  
18 page 11, if we could, please, you give us a bit of  
19 history here too:

20 "In 1959, it was discovered that a residue which  
21 remained in the bottle following transfusion of thawed  
22 plasma contained antihæmophilic factor, Factor VIII,  
23 activity."

24 That's Dr Judith Pool, whose name we have heard  
25 before:

1           "Factor VIII activity was able to correct  
2           haemostatic defect in Haemophilia A."

3           There is perhaps some potential for confusion,  
4           Dr Foster, in the references that we have had so far to  
5           freezing and thawing. In other words the haemophilia  
6           clinicians, when they have spoken about treating  
7           patients with cryoprecipitate, have spoken about thawing  
8           bags of cryoprecipitate in water baths at 37 degrees  
9           before you get something that you can inject into  
10          a patient, but obviously there are two freezing steps  
11          involved here, and to get the cryo in the first place,  
12          you start with frozen plasma. Is that correct?

13        A. That's correct, and what you are describing is the  
14          procedure that we used in the blood bank to prepare  
15          cryoprecipitate from a single donation, and that would  
16          begin with frozen plasma. The plasma would be thawed.  
17          During the thawing process the cryoprecipitate would  
18          form in the bag and then the cryoprecipitate would be  
19          extracted and then frozen down again.

20        Q. Yes.

21        THE CHAIRMAN: Sometimes, Dr Foster, it might help us to  
22          have a sort of physical picture painted. It might help  
23          our understanding of it. For example, you talk about  
24          fractionation quite a lot but people generally may think  
25          of fractionation in terms of the oil industry and of

1 very large columns that we see all over the place, or  
2 they might not know what it is at all. Similarly with  
3 the isolation of cryoprecipitate, it's sometimes helpful  
4 to have a picture of the actual physical process. It  
5 might communicate things.

6 A. Okay. In the blood bag that you are talking about,  
7 simply, when the block of plasma in the bag is thawing  
8 over a period of time, during that procedure there is  
9 a kind of sticky residue that forms that doesn't  
10 dissolve. It will dissolve if it gets warm enough but  
11 if you keep it cold it won't dissolve, and that residue  
12 can be harvested, if you like; it can be taken out and  
13 separated from the rest of the plasma. And that is what  
14 Judith Pool discovered, that she had this sticky stuff  
15 at the bottom of tube and she found it contained  
16 Factor VIII activity.

17 MS DUNLOP: If that's going to go to treat patients as  
18 cryoprecipitate, then you want the sticky stuff, you  
19 package it separately and then it's refrozen until it's  
20 needed for treatment. Is that right?

21 A. That's correct. I have to admit I have not worked in  
22 a blood bank, so I have never actually handled  
23 cryoprecipitate in that way that we are talking about.  
24 If you wanted somebody more expert it would be somebody  
25 like Dr Prowse or Professor Cash.

1 Q. I think that will do for now, Dr Foster. Just to say  
2 that when Dr Foster comes back as a witness in topic B3,  
3 we intend to do a more elaborate investigation of the  
4 different scientific processes. By that point we will  
5 want to take in viral inactivation as well.

6 THE CHAIRMAN: Yes. I don't want to get out of line but  
7 it's just this picture of Judith Pool's big step forward  
8 really; and there was a bit of background to that,  
9 wasn't there? She was trying to do some work for  
10 another laboratory and wondered where the Factor VIII  
11 was?

12 A. I can't say that I fully know the history of this but as  
13 far as I understand, it was kind of an accidental  
14 discovery, that there was this gungy stuff left behind  
15 and she took a look at it and found that it contained  
16 Factor VIII activity.

17 THE CHAIRMAN: Because the Cohn process had been different  
18 before that.

19 A. Yes, that was quite different and Edwin Cohn had been  
20 given the task of developing a substitute for plasma and  
21 he had identified albumin from plasma as a possible  
22 option for this, and he set about working out a means of  
23 recovering the albumin from the plasma, and to do that  
24 he had to remove the other plasma proteins and he used  
25 various techniques, basically based on solubility

1 differences between the different proteins, to remove,  
2 say, the proteins that were the least soluble and the  
3 proteins that had an intermediate solubility, and he was  
4 left with albumin, which is one of the more soluble  
5 proteins, and he called those different groups of  
6 protein fractions.

7 THE CHAIRMAN: That's something that I think we do all have  
8 to understand, that it was a progressive removal of  
9 proteins with different characteristics, ending up with  
10 Fraction V, which was albumin.

11 A. That's correct. And Cohn examined the different  
12 fractions and he looked at them to see if they would be  
13 effective with haemophilic plasma, if they could correct  
14 that defect, and he found that Fraction I would correct  
15 that defect and that became the basis of the very first  
16 Factor VIII concentrates that were the Cohn Fraction I.

17 THE CHAIRMAN: And Fraction I is what drew out these  
18 relatively large molecules of fibrinogen and fibronectin  
19 at the same time.

20 A. It's basically a heavy version of cryoprecipitate.

21 THE CHAIRMAN: Then Judith Pool comes along and  
22 accidentally, or otherwise, realises that she might get  
23 to the end product of the cryoprecipitate rather more  
24 quickly.

25 A. It was a simpler procedure than Cohn Fraction I and the



1 cryoprecipitate was a slightly better material.

2 THE CHAIRMAN: It had a better Factor VIII content,  
3 relatively?

4 A. It probably had a better Factor VIII content and it was  
5 less difficult to work with. It was slightly more  
6 purified.

7 THE CHAIRMAN: I know there is a great history which  
8 I thoroughly enjoy reading, but perhaps that sort of  
9 picture that you have painted helps us to get the  
10 context right.

11 MS DUNLOP: I wanted to pick up the thread with the gungy  
12 stuff or the gloopy stuff, whatever you want to call it,  
13 that is the cryoprecipitate, and we are now looking at  
14 the paragraph beginning:  
15 "Intermediate purity concentrates ..."

16 That that's not the end of the story, that you are  
17 going to go on and make concentrates. You are going to  
18 work with cryoprecipitate to do that, as I understand  
19 it. Is that right?

20 A. That's correct. Cryoprecipitate could also be obtained  
21 at what I'll call the industrial scale, where you are  
22 dealing with large quantities of frozen plasma and when  
23 you melt that plasma, the same material that you would  
24 get in the single blood bag would form in all of that  
25 plasma, and it can be collected because it has a heavy

1 mass. You can separate it in a machine called  
2 a centrifuge, which is like a spin dryer, and the solids  
3 settle in the spin dryer, and it's essentially the same  
4 type of material as Judith Pool had discovered but it  
5 could be the basis for beginning a further purification.

6 Q. What I had trouble picturing when I read this paragraph  
7 was the large-scale freezing. I think we can all  
8 imagine lots of donations of plasma mixed altogether in  
9 a pool but how did you --

10 A. The freezing is the same. The individual donations of  
11 plasma are frozen and then they have to have the plastic  
12 pack removed and then they have to go through a melting  
13 process, either by putting all the lumps into a big  
14 tank, and it's at that point that the cryoprecipitate  
15 forms.

16 Q. Right. And then with the cryoprecipitate, which you have  
17 obtained on an industrial scale, as I understand it,  
18 that is redissolved. Is that correct? Perhaps you  
19 should explain to us, rather than my trying to  
20 paraphrase it, but in simple terms, the next step to get  
21 to Factor VIII concentrate?

22 A. First of all you would collect the cryoprecipitate in  
23 the centrifuge and then when you had completed thawing  
24 all the plasma and you had all the cryoprecipitate in  
25 the centrifuge, which is refrigerated because it has to

1 be kept cold -- if it gets too warm it would redissolve  
2 and if it is too cold it freezes, so it has to be  
3 a controlled refrigeration. Once that is completed, the  
4 centrifuge is brought to a halt and the cryoprecipitate  
5 is removed, put into a vessel and various chemicals are  
6 added to redissolve the cryoprecipitate, and we called  
7 that a partial extraction because not everything  
8 dissolves; there would be some proteins that you would  
9 want to leave behind.

10 So a slight purification takes place at that point.  
11 Once that extraction has taken place, there are various  
12 other adjustments: you adjust the pH, you add in  
13 a chemical, which is a reagent to which some of the  
14 other coagulation factors that are still present stick,  
15 and can be removed.

16 Following that, there is another centrifugation step  
17 to clarify the material and some further adjustment, by  
18 adding chemicals, to stabilise the Factor VIII, and it's  
19 basically at that point that you get to what we call an  
20 intermediate purity Factor VIII.

21 Q. The last bit of this I want to ask you about is another  
22 freezing step, and it's the freeze-drying. That's  
23 presumably very near the end of the process?

24 A. Yes, once all of this chemical processing that I have  
25 described is completed, the solution is filtered through

1 a very fine filter to remove any bacterial contaminants,  
2 and it is dispensed aseptically in a sterile area into  
3 vials, then it would be loaded into a freeze dryer.  
4 Then within the freeze dryer, the material would be  
5 frozen, because the freeze dryer has a number of shelves  
6 which carry refrigerant, so you could freeze inside the  
7 freeze dryer and then carry out the freeze-drying  
8 process thereafter, which is the process for removing  
9 the water by a process of sublimation, where you miss  
10 out the liquid phase; you go straight from the solid to  
11 the gaseous phase by doing this under a vacuum.

12 And then at the end of the freeze-drying process the  
13 bottles or the vials would be sealed, still inside the  
14 freeze dryer because there would be stoppers that would  
15 be pushed home inside the freeze dryer to close  
16 everything inside the freeze dryer to maintain sterility  
17 inside the vial.

18 Q. One of the questions that I have seen, and I have to  
19 confess, on the Internet, but out there there are  
20 a number of different theories still around, and one of  
21 the questions is how a virus can survive after  
22 freeze-drying. But I suppose the answer to that is some  
23 do?

24 A. Well, freeze-drying is to preserve labile materials and  
25 viruses might be labile materials. So you use

1 freeze-dry to preserve viruses as well as proteins.

2 Vaccines might be freeze-dried to preserve their

3 activity.

4 Q. The other point I wanted to ask you, Dr Foster, just so  
5 we can understand, as his Lordship says, a little bit  
6 about the practicalities of it, trying to picture what  
7 happened, can we suppose a person gives a donation of  
8 blood, it would be, in Glasgow in 1980, that donation  
9 might have gone towards the treatment of people with  
10 haemophilia in one of two ways. It could have gone to  
11 the manufacture of cryoprecipitate or it could have  
12 ended up as Factor VIII concentrate. I just wondered if  
13 you could explain the practical steps that would have  
14 applied in relation to each. If you take the  
15 cryoprecipitate first. Suppose this is a donation  
16 somewhere in the centre of Glasgow?

17 A. If it was in the centre of Glasgow -- and I think the  
18 centre at that time probably was in St Vincent Street in  
19 Glasgow -- once the donation had been taken, the  
20 donation would be transported to Law Hospital, where the  
21 processing centre was, and the bag of blood would be  
22 centrifuged to sediment the cellular components, so you  
23 would have -- and I think Marc Turner has described this  
24 to you. At the bottom of the bag there would be the  
25 cellular components that really would look red and above

1           that there would be the straw-coloured liquid, which is  
2           plasma, and then the bag would be squeezed to squeeze  
3           out the plasma, which would go into another bag, and  
4           there were a number of bags interconnected to maintain  
5           sterility. Then the bag with the plasma in it would be  
6           taken away and frozen, still in Law Hospital. At some  
7           point it could either be taken to make cryoprecipitate  
8           in Law or it could be dispatched to PFC. And when bags  
9           came to PFC they would be boxed, I'm not sure how much  
10          there would be, 20 bags in a box, and we would get  
11          a lorry with a load of boxes that were all frozen. We  
12          had a refrigerated truck so that it would be kept frozen  
13          between Glasgow and Edinburgh and then it would be  
14          stored at PFC, frozen.

15        Q. So up until this point, the flowchart, as it were, it  
16          just has one stream and is it up to the people at Law to  
17          decide whether they are going to send the plasma to PFC  
18          or use it to make cryo?

19        A. Entirely.

20        Q. Right, okay. And suppose the former; suppose they are  
21          going to use it to make cryo?

22        A. That's not an area that I was involved in so I can't  
23          really go into --

24        Q. Okay, but they would do the whole process at Law?

25        A. They would do that themselves, yes.

1 Q. Then the plasma that they decide they are sending to  
2 Edinburgh comes through to Edinburgh. Still in 1980, it  
3 would have come through frozen?

4 A. That's correct.

5 Q. Does all Scottish plasma go in together?

6 A. Yes.

7 Q. Right.

8 A. There were periods when we actually separated Glasgow  
9 from Dundee or from Edinburgh; it goes back to the time  
10 when I was looking at investigating the quality of the  
11 plasma from different centres and we were trying to  
12 understand how to improve the Factor VIII contents of  
13 plasma, and we did, for a period, segregate the plasma  
14 from each centre but that was something we couldn't  
15 really do routinely. It was a special exercise.

16 Q. That would be the exception not the rule?

17 A. That's correct.

18 Q. On this page you have mentioned the commercial  
19 preparations, and from a table which you yourself  
20 include -- on page 46, but we don't need to go there,  
21 table 11 on page 46 -- it is pretty obvious that the  
22 first two commercial preparations licensed in the  
23 United Kingdom were a Hyland one, Hemofil,  
24 in February 1973, and a preparation from  
25 Immuno-in March 1973. I just wanted to ask you, because

1 I have asked several other witnesses, if you actually  
2 know why, given that Hyland seemed to have brought out  
3 a concentrate in America 1966, it was seven years before  
4 it was marketed in Britain?

5 A. I really have no answer for you other than to say that  
6 perhaps this was a learning process and it was  
7 a difficult manufacturing process and it took them that  
8 amount of time to learn how to do it to the extent that  
9 they could then distribute product around the world  
10 rather than just in the United States.

11 Q. I suppose what would have been particularly interesting  
12 would have been if there had been any attempt to  
13 introduce it in the United Kingdom which had failed, but  
14 you are not aware that that ever happened?

15 A. No, I have no knowledge of that.

16 Q. We have also seen reference, Dr Foster, in the  
17 Reverend Black's medical records to his being treated  
18 with four flasks of AHG in 1965. I don't know if you  
19 have seen that reference. I think that's maybe  
20 something which we could just note for the moment and go  
21 back to when we come to your more detailed history  
22 section. But in outline that's likely to have been an  
23 early Scottish product, is it?

24 A. I think that's most likely, yes.

25 Q. On the last paragraph on that page you record what



1 I think now doesn't surprise any of us, that the  
2 problems from the commercial products really related to  
3 the size of the pools and to the nature of the donors.  
4 So the fact that the donors were paid for giving their  
5 plasma and that the pools were very large.

6 Can we move on to the next page, please? You  
7 narrate some developments in 1973, and we have actually  
8 already looked at these. We looked at the establishment  
9 of the expert group and at the minutes of its first  
10 meeting. Self-sufficiency. You describe government  
11 policy, and we have looked at Hansard for January and  
12 indeed February 1975. I don't think there is any  
13 material difference, indeed what Dr David Owen said  
14 seems to be word for word the same on two occasions, and  
15 then you also refer to policy statement  
16 in December 1980, by Sir George Young, and I want to  
17 come back to that.

18 "The department of health has confirmed that the  
19 British Government supported recommendations on national  
20 self-sufficiency from the World Health Organisation and  
21 from the Council of Europe."

22 Next page, please. We have the  
23 World Health Organisation, and again we have looked at  
24 this, at the beginning of this block. Its  
25 recommendation, the resolution adopted in 1975.

1           Then you tell us about a WHO group of experts and  
2           they met in December 1975. You set out for us the final  
3           recommendations of the group. Again, we see emphasis on  
4           relying upon "voluntary unpaid donors", and then you  
5           mention also erythrocytes. Erythrocytes are the red  
6           cells?

7   A. That's correct.

8   Q. The reference to something called "component therapy"  
9           which I think we understand to mean, in crude terms,  
10          making good use of every single part?

11 A. Yes, that would be correct.

12 Q. Yes. Obviously using whole blood could be very wasteful  
13          because if the patient only really needs the red cells,  
14          then the other bits of the donation could go to treat  
15          somebody else?

16 A. That's right, yes.

17 Q. They could be used in a different way.

18           If we move on to the next page, please, I just  
19          wanted to ask you about the first bullet. On page 14;  
20          this is obviously a caution which is being expressed  
21          here:

22           "The long-term effects of repeated plasmapheresis  
23          ..."

24           And we understand what that is. That is about  
25          taking blood from the donor and then having the plasma

1 but returning the red cells to the donor, as  
2 I understand it. Is that right?

3 A. That's correct.

4 Q. And hyperimmunisation. I just wonder, how does the  
5 donor become hyperimmunised?

6 A. These are people who are deliberately given some  
7 injection to boost something like anti-D for example.  
8 That's my understanding of what that would mean.

9 Q. So you have obviously set out the relevant material from  
10 that report for us and then you have moved to  
11 a Council of Europe recommendation. I thought we should  
12 just look at that so that we have seen that. I don't  
13 think we have looked at that one before. It's  
14 [\[DHF0010507\]](#). You have quoted, Dr Foster, the first of  
15 the recommendations, which we can see there on the first  
16 page, it seems to be 1A, that:

17 "The governments of member states are to establish  
18 minimal criteria."

19 Do you think "minimal" is a slight mistranslation?  
20 I suppose "minimal" tends to connote that there is as  
21 little as possible. Do you think it may be minimum?

22 A. That may be what was intended.

23 Q. "... criteria for the quality, packaging, labelling and  
24 control of blood products for the treatment of  
25 haemophiliacs."

1           In terms of what's easily available, I couldn't find  
2           any legislation until the Blood Safety and Quality  
3           Regulations, but were there specifications in the  
4           United Kingdom relating to quality, packaging,  
5           et cetera, that were propounded by other bodies?

6   A.   There is the British Pharmacopeia, that has  
7           a specification of Factor VIII and Factor IX  
8           concentrates, and I think there were also  
9           World Health Organisation guidelines that were published  
10          in 1978, although I can't remember offhand if they  
11          covered all of these details.

12   Q.   But for Britain you would suspect that the mechanism  
13          would be the British Pharmacopeia?

14   A.   At that time I think that's correct.

15   Q.   Then 1(c):

16                 "The WHO are recommending the governments of member  
17                 states to inform all concerned in haemophilia therapy of  
18                 the problems arising from the procurement and rational  
19                 use of blood components concerned in order to balance  
20                 the needs and resources ..."

21                 I found that slightly delphic. Do you have a feel  
22                 for what that's really saying?

23   A.   I think it means try and make everyone work together to  
24          achieve this objective.

25   Q.   Perhaps that it's not an unlimited supply and it's

1 necessary to make the best use of what there is?

2 A. I think it was always recognised it was going to be a  
3 very difficult aspiration to achieve and therefore one  
4 would have to work closely right across the board, from  
5 the transfusion service to the haemophilia doctors, to  
6 make progress.

7 Q. Then in (ii) there is the reference, which you have  
8 quoted, to reaching, as far as possible,  
9 self-sufficiency of the member states, both in respect  
10 of anti-haemophilia products and blood plasma required  
11 for their preparation. So an international goal being  
12 expressed, I daresay not for the first time, but  
13 certainly being recorded in this 1980 resolution.

14 If we could go on to the second page, please.

15 Dr Foster, we have seen from the 1970s quite a lot of  
16 material showing that haemophilia clinicians in Britain  
17 very much ranked concentrates higher in their scale of  
18 preference than cryoprecipitate for treatment, and that  
19 last bullet looks to reflect the same sort of point. Is  
20 that right?

21 A. That would seem to be the case, yes.

22 Q. Then further down on the second page, if we see  
23 a paragraph beginning "quality control", we can note  
24 that there is a reference to the need -- and you have  
25 quoted this -- to reduce the risk of transmission of

1 hepatitis.

2 THE CHAIRMAN: Could I just ask a question at this stage?

3 The use of British Pharmacopeia as the way of  
4 disseminating definitions of Factor VIII/Factor IX,  
5 I rather understand that the Pharmacopeia is normally  
6 used for the benefit of pharmacies. Is that your  
7 understanding?

8 A. I'm not really sure about that. Certainly in terms of  
9 the blood products, the Pharmacopeia does lay out the  
10 specifications of what ought to be achieved. So it  
11 gives, for example, a purity and potency, and all of  
12 these characteristics are defined in the Pharmacopeia.  
13 So that for us would be the guideline that we would be  
14 working towards.

15 THE CHAIRMAN: You would quite happily resort to it for the  
16 specification?

17 A. We would, yes. Could I add that I think Mr Watt was on  
18 the Pharmacopeia committee at the time. So he was well  
19 aware of the discussions.

20 THE CHAIRMAN: Writing his own definition?

21 A. I wouldn't say that, no.

22 MS DUNLOP: Can we go back to Dr Foster's paper, please, and  
23 we are really on page 15. So that's [\[PEN0131125\]](#) at  
24 1139. You have set out the other two Council of Europe  
25 recommendations that we know are relevant in this area,

1 R(81)14 and then R(83)8, which relates to AIDS. The  
2 third bullet from R(83)8 reads:

3 "To avoid importation of blood plasma and  
4 coagulation factor products from countries with risk  
5 populations ..."

6 I have to confess, Dr Foster, I did check and that  
7 is certainly, word for word, what it says, perhaps not  
8 the best translation in the world. But I suppose it  
9 just means populations where the risks are thought to be  
10 higher, something like that.

11 A. I think at this time there was concern that blood was  
12 being collected in countries with populations that might  
13 have a higher level of hepatitis in their population and  
14 that that wasn't a desirable thing to do.

15 Q. Or, at this time, AIDS?

16 A. That's correct.

17 Q. Yes. Can we go on to the next page, please? You have  
18 referred to a statement of policy that's really quite  
19 a bit further on in time. Perhaps we can look at  
20 a document that seems to record this, [\[SGH0050501\]](#). You  
21 do mention this later on in the paper, so we will be  
22 looking at it a second time, but it is interesting to  
23 see what was being said by the Department of Health  
24 in October 1990. I think what you are quoting,  
25 Dr Foster, is a different reference but it's the same

1 formulation. Your reference is a letter to Mr Watters  
2 at the Haemophilia Society but we can see that the last  
3 sentence of this statement from the Department of Health  
4 says that:

5 "The principle of self-sufficiency, therefore, means  
6 that the supplies of domestically sourced blood products  
7 should be sufficient, both in range and quantity, to  
8 meet the needs of all patients whose clinicians prefer  
9 these to other available products."

10 So really quite a change from what seems to have  
11 been the understanding of self-sufficiency in the 1970s,  
12 and probably 1980s.

13 A. Yes, that was certainly different to the understanding  
14 that we had in SNBTS and I think it was something that  
15 Professor Cash was quite concerned about.

16 THE CHAIRMAN: There two aspects to it. There is the policy  
17 of community self-sufficiency. What do you understand  
18 that to refer to?

19 A. That refers to the European Community.

20 THE CHAIRMAN: So that, so long as there was enough of  
21 a blood product in the community as a whole,  
22 self-sufficiency was met, irrespective of whether  
23 individual states were --

24 A. You could interpret it that way, yes.

25 THE CHAIRMAN: That may be the interpretation of the



1 first paragraph. The second is that self-sufficiency  
2 seems to depend on some sort of residual demand, after  
3 each individual clinician has decided whether or not he  
4 wants to use alternative products.

5 A. That's certainly how it reads, yes.

6 THE CHAIRMAN: How do you work within that sort of  
7 framework?

8 A. I think that's why Professor Cash was so concerned about  
9 this.

10 MS DUNLOP: Was it around about 1990 that was the first time  
11 you had ever heard it expressed in this sort of way?

12 A. Yes, it was. It was certainly the first time we had  
13 seen anything in writing along these lines. But this is  
14 really an aspect you should ask Professor Cash more  
15 about than myself.

16 Q. We shall, but you mention the timing of this later in  
17 your paper and it may be that it has some relationship  
18 to the government reporting that it had achieved  
19 self-sufficiency around about this time -- in the UK  
20 Government?

21 A. Yes, there was a survey carried out by  
22 Professor van Aken for the European Community shortly  
23 after this, in which he was dealing with what had been  
24 achieved in different countries, and he quoted this  
25 definition of the UK and saying that the UK had declared

1           that it had achieved self-sufficiency according to this  
2           definition.

3   Q.   Yes.  We will come back to that, I think, Dr Foster.

4           Then you have dealt in your paper -- perhaps we could go  
5           back to that, please -- with VCJD.  Then can we move to  
6           the next page, please, "Policy into practice".  You say:

7                   "Achieving national self-sufficiency using local  
8           plasma from volunteer, non-remunerated donors is not  
9           straightforward."

10                   Easy to state, difficult to achieve, doctor?

11   A.   I think the evidence on that is very clear, that if you  
12           look worldwide, I'm not really sure any country has  
13           really ever achieved that with Factor VIII concentrate.

14   Q.   Then can we go on to the next page, please?  You make at  
15           the top what I understand is perhaps an important  
16           difference, that national organisations have an  
17           additional hurdle that commercial companies don't face,  
18           namely that national organisations are trying to achieve  
19           use of only volunteer donations and produce all products  
20           in quantities sufficient to treat their whole  
21           population, which, obviously, commercial companies don't  
22           have to worry about.  They, presumably, just make as  
23           much as they think they can sell?

24   A.   There is a different framework completely, obviously,  
25           from the two types of operation.  But there is one other

1 aspect that is really fundamentally important and that  
2 is the different way in which plasma is supplied, let's  
3 say, in Scotland in the volunteer system, compared to  
4 the United States, and I think that was discussed  
5 earlier in this paper, which is really the volumes that  
6 can be obtained by plasmapheresis from a commercial  
7 donor in the United States, where the donor could give  
8 600 millilitres twice a week, which is 1.2 litres  
9 a week, every week, compared to the Scottish situation,  
10 where we had a whole blood donor, who at best would give  
11 twice a year and you would get half a litre from that  
12 donor.

13 So there is a difference in terms of productivity of  
14 the donor, if I can put it that way. The commercial  
15 donor is 100 times more productive than the Scottish  
16 donor. By that I mean the commercial donor in the  
17 United States because no other country in the world  
18 takes plasma in that volume from its citizens, and that  
19 was unique in the United States then and it remains so  
20 today.

21 Q. And you have dealt with that also later in your paper.  
22 You have set out these specific limits. You make  
23 a point too in the last sentence of this paragraph that  
24 they, that is national organisations:

25 "Lacked a team of sales and marketing

1 representatives to promote their products and offer  
2 clinicians support for research and attendance at  
3 meetings."

4 Even simple things, Dr Foster, packaging has been  
5 mentioned; I think there was a reference to some of the  
6 commercial manufacturers producing a little box which  
7 had in it everything the patient might need. Presumably  
8 that sort of thing is easier for a commercial company?

9 A. Well, commercial companies were competing in  
10 a marketplace and they were doing their best to provide  
11 attractive products. So I think it's understandable  
12 they would be doing a lot of work into packaging as well  
13 as the product.

14 For us in the health service, we would just have to  
15 be quite clear about it. We didn't have budgets that  
16 would cover that kind of thing and we were hoping or  
17 expecting that haemophilia centres would provide  
18 appropriate bits and pieces that were required for the  
19 treatment of the patient over and above what we  
20 provided. If someone had come to us and said, "Look, we  
21 really need this, can you give it to us," we would have  
22 addressed that but I'm not aware that that happened.

23 Q. You mention, obviously, in this sentence support for  
24 research and attendance at meetings. That's financial  
25 support, so paying for doctors to travel to conferences

1           abroad and that sort of thing. That's what you mean?

2    A. I think that's generally what happened, yes.

3    Q. What effect does that have in your estimation?

4    A. I don't really want to comment on that.

5    Q. Then I wanted to note from the next paragraph

6           "forecasting product demand". You say that what was not

7           readily predicted was how the availability of

8           concentrates would change practice and drive up demand.

9           And I think we understand that it was a situation in

10          which success bred success really?

11   A. I think that's a very good way to put it, yes.

12   Q. And then on to the next page, "Supply of plasma". I

13          didn't want to ask you anything specific about this

14          page, Dr Foster, but you are making points to do with,

15          firstly it's only really the freshest plasma,

16          fresh-frozen plasma, that was suitable for the

17          manufacture of concentrates. So quite an important time

18          factor that comes in really from the start?

19   A. Yes, that's correct. There was a time when the

20          transfusion service would send blood out to hospitals

21          and if it wasn't used it would come back, and you could

22          recover the plasma but you couldn't make Factor VIII

23          from it because it was too old. You could recover

24          albumin but not Factor VIII. So to get Factor VIII you

25          have to process the plasma much more quickly.

1 Q. Then you make the point you have just explained at the  
2 bottom of that page:

3 "The volume of plasma that could be obtained by  
4 a plasmapheresis from a donor restricted to 12 litres  
5 per annum."

6 In practice, I think, from what you said a moment  
7 ago, it would be unlikely to achieve 12 litres per  
8 annum?

9 A. This was in the UK. If we were to use plasmapheresis,  
10 those would have been the guide allowance that would  
11 have been followed in the UK. In practice, prior to  
12 1990, we didn't collect fresh plasma by plasma pheresis;  
13 we just used the whole blood donor.

14 Q. So you are just at the two donations a year, which is  
15 1 litre per year?

16 A. Half a litre.

17 Q. I thought it was half a litre each?

18 A. Quarter of a litre each donation.

19 Q. Half a litre in total?

20 A. From one donor in a year.

21 Q. Then you say that in the United States of America, it  
22 was possible to collect up to 60 litres per annum per  
23 donor.

24 On to the next page. Look at the section on  
25 manufacturing capability. Many different products from

1 a complex starting material, needing dedicated  
2 facilities, specialist facilities, temperature control,  
3 use of specialist equipment, reagents, other materials.  
4 A research and development capability too, and that's  
5 the area in which you have worked prominently.

6 A. That's correct.

7 Q. You refer in the last paragraph to what was done in some  
8 countries, for example, Norway, that they achieved  
9 self-sufficiency but not by doing it themselves. They  
10 collected the donations and sent them elsewhere to be  
11 processed?

12 A. That's right.

13 Q. But the difficulty with that would be that essentially  
14 you would be mixing plasma from your own country with  
15 the plasma from whatever country the facility --

16 A. That's correct, yes.

17 Q. I suppose one of the ideas, or one of the less desirable  
18 aspects of that is that you are opening up the  
19 possibility of viruses, which may be contained within  
20 a particular country or confined within particular  
21 borders, mingling on a much wider geographical scale?

22 A. Yes, there is that possibility, yes.

23 Q. Then "Management processes (Scotland)", if we move on to  
24 the next page, please. So here you are telling us how  
25 matters in Scotland were organised and you say that:

1           "There were meetings between officials of the SHHD  
2           haemophilia directors and SNBTS directors."

3           We have seen those. Obviously slightly sporadic,  
4           a bit of a gap between 1977 and 1981 and then between  
5           1981 and 1983. Perhaps we could have a look at the 1977  
6           meeting. I don't think we have looked at that. It's  
7           [\[SNB0015033\]](#).

8           You are not at that. I suppose the directors of  
9           SNBTS and the haemophilia directors with government  
10          involvement. We can see that it's around about the time  
11          when Major General Jeffrey had died, he having been the  
12          National Medical Director. If we just scroll down  
13          page 1, please, we can see what's on the agenda. Look  
14          in particular at page 2 and section 7 at the bottom,  
15          please.

16          Mr Watt. Presumably from the time you started there  
17          will have always been a hunger for supplies. This  
18          sounds as though Mr Watt has been pleased to receive  
19          some more from the West of Scotland but Dr Wallace is  
20          saying that that has really only been possible because  
21          he has purchased a substantial amount of commercial  
22          concentrate to help overcome the initial transitional  
23          phase.

24          So a certain paradox, I suppose, Dr Foster, in that  
25          PFC is wanting more plasma to assist in achieving the



1 goal of self-sufficiency, and that's the production of  
2 more plasma or the sending of more plasma from west to  
3 east, has been achieved because in the west, some  
4 commercial product has been purchased. But I suppose  
5 that may have been seen as a transitional arrangement,  
6 something that might not be a permanent policy?

7 A. This situation is really just after the start-up of PFC,  
8 which we began in 1975 and we were commissioning the  
9 plant, and PFC, it may not be appreciated, was actually  
10 designed to provide albumin and when it was built,  
11 Factor VIII wasn't really on the agenda because the  
12 Biggs MRC working party hadn't decided what was  
13 required.

14 The real drive to begin with was to provide albumin,  
15 and because there was a shortage of albumin in Scotland,  
16 Glasgow BTS were providing freeze-dried plasma in quite  
17 large quantities, and it wasn't until we could provide  
18 them with albumin that they could stop providing  
19 freeze-dried plasma and that plasma then became  
20 available to recover Factor VIII as fresh-frozen plasma.

21 So there was this knock-on effect, that we first had  
22 to provide the albumin then they could stop making the  
23 freeze-dried plasma and then we could get more plasma to  
24 make Factor VIII. That's why this, what might appear to  
25 be a prolonged start-up phase of PFC, took place and of

1 course this was at the time when in  
2 Glasgow Royal Infirmary there was a keenness to start  
3 patients on home therapy and this correspondence that  
4 shows that they want to start home therapy, so they go  
5 and buy commercial, so they can do that.

6 THE CHAIRMAN: I have a problem trying to sort out in my own  
7 mind where the blockages might have been round about  
8 this time, Dr Foster. I see from what you have said  
9 that there is a tension between getting PFC into full  
10 commissioning and operation and the effect on the supply  
11 of plasma. I am also of the impression that there was  
12 a preference for particular approaches to therapy in the  
13 West of Scotland that might be different from the  
14 objectives of PFC, and that cryoprecipitate in  
15 particular was a favoured therapeutic material. Do you  
16 remember that as a factor?

17 A. I have noticed that coming out in some comments, that  
18 there seems to be a view that Glasgow were keen on  
19 preparing cryoprecipitate and they did have a programme,  
20 after this actually, for trying to develop  
21 a freeze-dried cryoprecipitate. But the clinicians  
22 weren't really that interested in cryoprecipitate, they  
23 wanted concentrate. So I think there was a period here  
24 where people were trying to understand what was required  
25 because the demand and the use was actually going into

1 territories that nobody had predicted.

2 THE CHAIRMAN: Yes. It may be one of these things it's very  
3 difficult to disentangle retrospectively from the odd  
4 recorded comment but I would like to try to get the  
5 atmosphere if I could.

6 A. I think, unless the participants can be brought back  
7 from the grave, then I think it's impossible.

8 THE CHAIRMAN: My powers are extensive but they don't cover  
9 that particular method of getting information. Yes.

10 MS DUNLOP: Can we just go on to the following page, please:

11 "Dr George McDonald of Glasgow Royal Infirmary  
12 complimented Mr Watt and his staff on their achievements  
13 over the past 12 months."

14 The word "optimistic" is actually used in  
15 paragraph 7, Dr Foster. Would it be right for us to  
16 think of this as a time when people were optimistic  
17 about what could be achieved?

18 A. PFC had only just opened and it was opened with some  
19 kind of an expectation that this was going to solve  
20 everyone's problems, and of course that didn't happen  
21 because the targets that had been set turned out to be  
22 not what happened. The demand went up and up and up and  
23 up and really we were just chasing this ever-increasing  
24 demand as hard as we could and Dr Cash was banging the  
25 drum to get more and more plasma, and we were doing

1 everything we could to produce more and more, but of  
2 course the aspirations of the doctors and the patients,  
3 which one can understand, is that this was so successful  
4 that they were running ahead of us all the time.

5 Q. Yes. We can see this particularly Dr Foster, I think,  
6 when we come to look at some of tables, it certainly has  
7 the feel of a race in which you are trying to catch the  
8 person in front of you and it's very difficult even to  
9 draw alongside because they are always pulling ahead.

10 A. That's exactly right, yes. They were kind of always  
11 disappearing over the horizon.

12 Q. Yes. Can we go back to the paper, please? We have  
13 already looked at the minutes of the joint meeting  
14 in January 1981 and just to note that, as you say, at  
15 that meeting the Council of Europe recommendation was  
16 discussed. So even if it might be difficult -- and we  
17 haven't really gone into this in any detail, it might be  
18 difficult to find express statements of the policy of  
19 self-sufficiency for Scotland by politicians or by  
20 government; there doesn't seem to be any doubt that  
21 everybody knew that that was the aim in Scotland?

22 A. Certainly I would say that 1981 meeting there seemed to  
23 be quite a consensus and complete agreement that that  
24 was the objective we were all working towards.

25 Q. Right. From national management processes you go on to

1 discuss SNBTS management processes, and you explain that  
2 there was a blood transfusion subcommittee of the  
3 Common Services Agency and then that the directors met  
4 themselves with SHHD in attendance, and you explain  
5 about the organisation of the chairing of the meetings  
6 of the directors. Can we go on to the following page,  
7 please?

8 Just to note that you also have a section on  
9 management at PFC and we have noticed -- and it's  
10 discussed in the preliminary report -- that there was  
11 a Factor VIII study group created -- and I think that's  
12 1982 -- and that that itself had various subgroups.

13 A. That's correct. That was John Cash's initiative and it  
14 began in January 1982.

15 Q. Yes. Section 3 is Factor VIII demand and you have  
16 looked first at forecasts of demand.

17 THE CHAIRMAN: Ms Dunlop, are we having a break this  
18 morning?

19 MS DUNLOP: Yes.

20 THE CHAIRMAN: I know that timing has got out of line  
21 a little but I'm still anxious that we should break the  
22 morning up in a way that suits the stenographer best and  
23 if you are going on to another major new topic, it might  
24 be better. I'll take your guidance on it.

25 MS DUNLOP: I'll try and stop at a natural break, sir.

1           Factor VIII demand. You refer to the forecasts of  
2           1973. Then reading on to the next page, the MRC working  
3           party:

4           "An assessment of the total amount of Factor VIII  
5           likely to be required for all types of treatment puts  
6           the total in excess of 500,000 blood donations for about  
7           40 million units of Factor VIII."

8           Dr Foster, I worked out, so it might be wrong, but  
9           I worked out that this arithmetic suggests that you  
10          would be expecting about 80 units per donation. This is  
11          the 40 million units from 500,000 blood donations. That  
12          would be 80 million units from 1 million donations,  
13          which would work out at 80 units per donation. That's  
14          the assumptions they are making.

15        A. There is an assumption here about what's in  
16          cryoprecipitate. And one of the difficulties with  
17          cryoprecipitate is that you couldn't actually assay it,  
18          you couldn't measure the Factor VIII content every time.  
19          You could only go on some samples that might be taken.  
20          I think it may be -- and I'm not sure it is clear in any  
21          of these documents -- that that was the assumption, that  
22          that was the yield in cryoprecipitate at that time from  
23          one bag of cryoprecipitate. I have to say, I think  
24          cryoprecipitate was quite variable in its content. So  
25          they might have assumed the lower level just for safety

1 purposes in terms of making sure that the patient got an  
2 adequate treatment.

3 Q. Thank you.

4 We can see at least steadily rising targets.  
5 Sometimes targets are expressed as absolute numbers of  
6 donations, sometimes as numbers of international units  
7 per head of population. Would it be correct to think of  
8 the end point of this -- and this is the race with the  
9 runner disappearing over the horizon again, but the end  
10 point, I suppose, was going to be when all those with  
11 severe haemophilia in the United Kingdom were on  
12 prophylactic treatment and there was also enough to  
13 supply the additional requirements for people with  
14 moderate and mild haemophilia and for acute incidents  
15 requiring specific treatment as well?

16 A. I'm not really sure that that had been thought through  
17 at this point in time because people were still learning  
18 what they could do with this stuff and thinking, "What  
19 more can we do with it?" I'm not really sure that even  
20 at this time these working parties really fully  
21 understood how far it was going to go.

22 Q. But I suppose if they had had a crystal ball they would  
23 have been able to say to themselves, "This is, in the  
24 end, what we are going to be required to satisfy"?

25 A. If they had had a crystal ball, yes.

1 Q. I noticed in Professor Hann's statement that he urges  
2 the Inquiry to bear in mind, when considering  
3 self-sufficiency as a topic, that prophylactic treatment  
4 in a child with severe haemophilia would take 6,000  
5 units per kilogramme of body weight per year. So just  
6 working that through, and thinking about 1980 -- if we  
7 could move down the page and look at forecasts of demand  
8 for Scotland.

9 Just to give ourselves an idea of how the figures  
10 panned out, if you imagine that the 55 Haemophilia A  
11 patients who were registered at Yorkhill in 1980,  
12 suppose 25 of them had severe haemophilia, then that  
13 would be 25 at whatever would be a reasonable weight to  
14 take, and I'm unashamedly going to give evidence here  
15 and say that a reasonable weight for an average 9 or  
16 10-year old child, so a mid-aged child, might be 30  
17 kilogrammes. So you would be talking about 25 children  
18 at an average of 30 kilogrammes all needing 6,000 units  
19 per year and that actually works out at 4.5 million  
20 units. So that would be just that very small group of  
21 patients with haemophilia in Scotland. So I think that  
22 just gives us some sort of idea of how far ahead the  
23 runner was perhaps going to pull.

24 A. Yes. It also indicates how far ahead that type of  
25 treatment was compared to the thinking that was taking



1 place at this time. The people actually hadn't -- the  
2 thinking hadn't gone that far. I suspect that what was  
3 happening is that they were tending to look at what had  
4 been used in the past and then extrapolating from that  
5 without trying to calculate -- or looking into the  
6 future and saying, "What do we think would be required  
7 in the future?" And I think the first person who sat  
8 down and did that was probably John Cash.

9 Q. Right. So indeed, having done that calculation, and  
10 worked out that you would need 4.5 million units just to  
11 meet that portion of the need at Yorkhill, it's then  
12 interesting to juxtapose it with the estimate that  
13 equated to a total of 4 million units of Factor VIII per  
14 annum for Scotland, which is from the mid 1970s.

15 But we can see that the target did increase and you  
16 have taken us through that. Moving to a different  
17 measuring system, moving from a target of 1.8 units per  
18 head of population per annum, 1981, 2.75 units per head  
19 of population per annum, 3.75 units per head of  
20 population by 1996. If we look at the table, which is  
21 on the next page, table 1, you have given us the amount  
22 of Factor VIII used each calendar year in the  
23 United Kingdom since 1970, and we can see the figures.  
24 Over that 35-year period, 1970 to 2005, if we just look  
25 at the column on the furthest right, which is

1 international units per head of population, it has gone  
2 from 0.15 in 1970 to 4.73 in 2005. So very roughly, in  
3 a 35-year period it has increased about 35-fold; a big  
4 increase.

5 A. You could say that, yes.

6 Q. Yes. So the runner behind wouldn't just feel that he  
7 was trying to catch someone in front, he would feel he  
8 was running uphill at the same time?

9 A. Running uphill and trying to sprint faster as well.

10 Q. Yes. We move to the next page where you note a number  
11 of points from this table. Those of us with hard copies  
12 can unpick them and put them side by side, if that's  
13 easier.

14 You say that:

15 "An almost continual year on year increase in the  
16 treatment with Factor VIII ... reduction in the use of  
17 cryo ... marked use of imported commercial concentrates  
18 from 1974 ... year by year increase in the use of  
19 commercial concentrates from 1974 to 1982."

20 Of course this is a UK table:

21 "A decline in the use of commercial concentrates,  
22 1983 and 1984 ..."

23 Substantial reduction in the supply of NHS  
24 Factor VIII in 1985 to do with heat treatment. Then  
25 back to an increase in the use of commercial

1 concentrates in 1985 and so on.

2 You say:

3 "A reduction in the use of cryoprecipitate was  
4 consistent with guidance in the 1970s from expert  
5 advisory committees and UK haemophilia directors, whilst  
6 importation of commercial Factor VIII concentrates was  
7 recommended by haemophilia directors and by the UK  
8 Haemophilia Society."

9 Then, an amount of Factor VIII used in Scotland.

10 You say:

11 "The UKHCDO does not normally provide a breakdown of  
12 the treatment of people with haemophilia in different  
13 parts of the UK."

14 But you have some data for the period 1978 to 1984  
15 and we can see that on the next page, table 2. Again,  
16 an almost year on year increase, reduction in the use of  
17 cryoprecipitate, some use of commercial concentrates.  
18 We can always look back and see how these figures  
19 compare with the United Kingdom. You have gone on to do  
20 that. You said:

21 "A direct comparison between Scotland and the rest  
22 of the UK can be made for that period."

23 That's table 3. Go on to the next page. There  
24 didn't seem to me to be anything particularly worthy of  
25 note in the comparison, Dr Foster, save perhaps that in

1           1980 and 1983, the totals for Scotland are more than  
2           they are for the rest of the UK, and for the other years  
3           it is really the other way round but not huge  
4           differences. This is looking at at least the first two  
5           columns of numbers. I think that would be all that one  
6           would take from that perhaps.

7    A. Yes. I think you will see this later on in table 16,  
8           where there was a doubling of use of Factor VIII in one  
9           year in Scotland.

10   Q. Yes. 1980, in fact.

11   A. That's right.

12   Q. But what is remarkable in this table are column 3 and  
13           column 4. They really speak for themselves. I think,  
14           as usual, Dr Foster, you have said what I'm trying to  
15           say in your text --

16   A. I should point out the footnote to the table. That  
17           includes cryoprecipitate.

18   Q. Yes, indeed. But you have said that the total amounts  
19           are not that different but the difference in the origin  
20           of Factor VIII was more substantial, with 88 per cent.  
21           You have just averaged the seven years that you have  
22           tabulated, have you?

23   A. Yes.

24   Q. That:

25           "The 88 per cent used in Scotland being obtained

1 from the NHS compared with 44 per cent in the rest of  
2 the UK. With 12 per cent and 56 per cent being imported  
3 from commercial sources respectively."

4 That seems to be a good point at which to break,  
5 sir, if that's suitable.

6 THE CHAIRMAN: Yes.

7 (11.18 am)

8 (Short break)

9 (11.45 am)

10 THE CHAIRMAN: Can I ask just a little about plasmapheresis?

11 MS DUNLOP: Oh, right.

12 A. There is a big section in the paper on plasmapheresis,  
13 sir.

14 THE CHAIRMAN: On the history of it? If we are coming back  
15 to it? If we are, I won't bother.

16 MS DUNLOP: A little further on, there is a section on  
17 plasmapheresis. Section 4.2.1.

18 THE CHAIRMAN: I'll ask my few questions when I get to  
19 there. I think they fit in quite well. I have some  
20 references to 1981 and the study of plasmapheresis in  
21 Belgium, for example. Did you take part in that?

22 A. No, I didn't take part in that.

23 THE CHAIRMAN: We will come back to it in due course.

24 MS DUNLOP: Dr Foster, I think just before we stopped we  
25 were looking at forecasting on page 27. So back to your

1 paper. [\[PEN0131125\]](#) at 1151, section 3.6, "Accuracy of  
2 forecasts".

3 You have tabulated for us the particular forecasts  
4 made and essentially how long they lasted. So the DHSS  
5 expert group who made a forecast in 1973, their forecast  
6 was exceeded in 1977. Likewise, the MRC working party,  
7 the DHSS working group who made a prediction in 1977,  
8 theirs was exceeded in 1982 and so on.

9 Look on the next page, 1981, the haemophilia  
10 directors, their forecast wasn't exceeded until 1990.  
11 Then the one of 2.6 million international units per  
12 million members of the population was exceeded in 1996.  
13 Then the ones for Scotland, certainly the one made in  
14 1981 by Professor Cash seems to have lasted for  
15 a reasonably long time, 1981 to 1997.

16 Your commentary on these is at 3.6.2. You say:

17 "The first set of estimates, either for the UK or  
18 for Scotland, failed to anticipate long-term growth in  
19 usage."

20 One of the problems was that the collection of data  
21 necessarily, I suppose, retrospective, and only usually  
22 available some ten months later:

23 "At a time of strong growth in usage, reliance on  
24 these data could be misleading. This is illustrated by  
25 an editorial in the BMJ."

1           We do have that. That's [\[PEN0160329\]](#).

2           At the beginning there is a contrast drawn between  
3 cryoprecipitate and freeze-dried Factor VIII. The  
4 advantages of the latter being highlighted.  
5 Haemophilia centre directors generally agree that most  
6 if not all of the material used to treat haemophilia in  
7 Britain should be freeze-dried concentrate, preferably  
8 made within the NHS. Nothing we haven't heard before,  
9 Dr Foster. Then on to the next page, the amount still  
10 falls far short of the needs of haemophiliacs. The  
11 writer of this is making the point that:

12           "Commercial concentrates are costing about 10 pence  
13 per unit of Factor VIII activity. This is money that  
14 many experts think would be better spent in promoting  
15 the manufacture of Factor VIII and other important  
16 plasma fractions within the NHS."

17           But I think the particular reference you make to  
18 this editorial, Dr Foster, is further down this page,  
19 where the writer is wondering why self-sufficiency  
20 hasn't been achieved. We can see that:

21           "Why is this? It is not lack of skill, it is not  
22 lack of fractionation facilities."

23           It is really that phrase that you have highlighted  
24 for us:

25           "... though, to meet the target of 40 million units

1 of freeze-dried Factor VIII per annum ..."

2 I think the point you were making was that the  
3 writer of this is talking about the problem of not  
4 producing enough but actually they are talking in terms  
5 of a target which is itself inadequate.

6 A. The point I'm making is that when this was written, the  
7 actual use was 45 million units, so the author was  
8 already out of date.

9 Q. Yes. Do you agree with the author's explanation? Even  
10 with adequate financial support it is difficult to  
11 switch from relatively small scale to very large-scale  
12 production in under five years?

13 A. I think there were different difficulties in different  
14 parts of the UK. Certainly in Scotland, the greatest  
15 difficulty was obtaining plasma, whereas in England the  
16 greater difficulty became having facilities for  
17 fractionation as well as plasma.

18 Q. So both north and south of the border, as we always say,  
19 having enough plasma was a constant problem and then the  
20 lack of facilities in England was an additional  
21 difficulty.

22 A. That's correct.

23 Q. Yes. Can we go back to the paper then, please, at  
24 page 28?

25 You make the point that to calculate the amount of



1 plasma required, it was necessary to know the yield of  
2 product. I think we can understand that, that  
3 essentially this is a process of working backwards. If  
4 you know the number of units that you want to achieve to  
5 treat patients, and you know what the starting material  
6 is, obviously you have to have an assumption for what  
7 proportion of the material you want, you can derive from  
8 the starting material. I think you go on to tell us  
9 that the estimates that were used for yield, or the  
10 assumptions that were used for yield, were a bit  
11 over-optimistic. Is that right?

12 A. That seems to be the case, yes.

13 Q. You instance the MRC working party, their assumption of  
14 a yield of 37 per cent, Colonel Jeffrey assuming a yield  
15 of 40 per cent, and you go on to say that:

16 "The actual yield was much less than had been  
17 assumed. So estimates of the amount of plasma to be  
18 collected and the processing capacity needed were both  
19 about half of what was required."

20 And that was before the growth had been taken into  
21 account?

22 A. Yes, and of course, this was at a time when  
23 manufacturing intermediate purity Factor VIII in the UK  
24 was really a new activity and people didn't really have  
25 the experience to know what the yield was going to be.

1 Q. Can we go on to the next page, please? Two main reasons  
2 for the overestimation of yield. One was an  
3 under-appreciation of how much would be lost in the  
4 simple scaling-up of the work. You say it was a greater  
5 loss during the additional time needed to process larger  
6 volumes?

7 A. Yes, I think everyone understands that Factor VIII was  
8 a sensitive material and therefore the longer you took  
9 to carry out the process, the less you would have at the  
10 end, regardless of other difficulties that you come  
11 across at increased scale of manufacture.

12 Q. Yes. Then the second reason was a change to the method,  
13 the assay used in the UK by which the activity of  
14 Factor VIII was measured. I think it would help,  
15 Dr Foster, if you explain this reason to us a little  
16 more fully because I certainly didn't find it  
17 particularly easy to grasp: why a change in measurement  
18 made a difference.

19 A. Yes, we are talking about the assays that were used to  
20 measure the Factor VIII activity. I think you have  
21 heard that there were basically two types of assay. One  
22 was called a one-stage, the other one was called a  
23 two-stage. You don't need to know the details of that,  
24 except to know that there was a great deal of variation.  
25 These are not very precise measurements and at this

1 time, even in the best laboratories, there was an error  
2 of about 40 per cent in the assays and there were  
3 differences between laboratories. At NIBSC they were  
4 very keen to try to have some standardisation so that  
5 there would be more uniform measurements; and this would  
6 be in haematology laboratories as well as in  
7 fractionation centres.

8 So there was this workshop of all the people brought  
9 together in the UK by NIBSC, where each group carried  
10 out the assay using their own procedure and comparisons  
11 were made, and they gradually worked out where the  
12 differences were occurring and tried to come up with  
13 a more standard procedure. In doing that they changed  
14 some of the reagents that were being used and also, what  
15 is called a standard, which is the reference material  
16 that you use to calibrate the assay. That was changed.  
17 Putting all these changes together, the outcome for us  
18 and for BPL was that we apparently had a reduction in  
19 the value of Factor VIII that we measured, which was  
20 seen as a reduction in yield.

21 Q. That was true even though there might not have been an  
22 absolute reduction in yield. The same sample measured  
23 before and after the change of methodology might in fact  
24 have the same proportion in it --

25 A. That's exactly right. We would have exactly the same

1 material measured both ways and you would have one value  
2 that was, say, 100 and one value that was 120 and  
3 therefore the value that was 100 would be taken, not the  
4 value that was 120, whereas in the past it would have  
5 been the 120 that you would have taken.

6 Q. Right.

7 A. So this is actually a more conservative assay than the  
8 previous assay.

9 Q. Yes. You go on to tell us what the net effect of all of  
10 this was. This is the paragraph we can see on the  
11 screen:

12 "Instead of a yield of 40 per cent assumed by  
13 Colonel Jeffrey in 1976, the overall routine yield by  
14 1976/1977 was only 20 per cent. This in turn fell to  
15 15 per cent when the full impact of the change in assay  
16 procedure was experienced. This resulted in the amount  
17 of plasma needed to meet the targeted output of  
18 Factor VIII being increased 2.6 fold."

19 A. There is one thing that I haven't explained in this  
20 paragraph. I do mention samples for quality control but  
21 it might help you to appreciate the quantitative impact  
22 of that. Because at this point in time we were  
23 manufacturing a batch of Factor VIII that would contain  
24 about 150 vials of Factor VIII, and to carry out the  
25 quality control sampling that was required we would have

1 to remove about 25 vials from that batch. So you are  
2 actually consigning, for quality control, quite  
3 a significant proportion of the batch.

4 Q. Yes.

5 A. And the only way to reduce that impact, because this  
6 number of samples is fixed, was to increase the batch  
7 size, which is something that we went on to do.

8 Q. But you say that this resulted in the amount of plasma  
9 being increased 2.6 fold. That's just because, to get  
10 from 15 up to 40, you need to multiply by two and  
11 two-thirds.

12 A. That's right.

13 Q. That's the process?

14 A. Yes.

15 Q. Yes. For Scotland, the demand predicted in 1975 was  
16 exceeded in 1980, and you go on to give us some more  
17 detail on estimates and when they were exceeded. Read  
18 on to the next page. This is both UKHCDO estimates and  
19 SNBTS estimates that were more accurate:

20 "They predicted continued growth in usage over  
21 a long period of time, however, in both cases the actual  
22 rate of growth was much slower than predicted."

23 So the rate of growth in fact was slower?

24 A. I'm going back to the table earlier where there was  
25 John Cash's estimate, where he said we would expect to

1           have 2.75 million units by 1986. In fact that was a bit  
2           of an overestimate because the actual amount reached  
3           that point some years later.

4    Q.   Yes. Actually that was table 4, that his prediction was  
5           2.7 by 1986 and that wasn't in fact exceeded until 1997?

6    A.   Yes, that's what I'm getting at here.

7    Q.   Section 4 "provision of plasma". You alluded to this  
8           earlier. There might have been three different types of  
9           plasma but only one of them, fresh-frozen plasma, could  
10          be used to prepare Factor VIII concentrate. And no  
11          doubt Factor IX as well?

12   A.   That's correct.

13   Q.   Because you were working with the same stuff. So you go  
14          on to tell us that given that restriction, there were  
15          a number of strategies used to obtain fresh-frozen  
16          plasma, the first of which was to increase the number of  
17          donations. We can understand that. I don't know if you  
18          call it advertising. It sounds funny to call it  
19          advertising when you are trying to encourage people to  
20          give blood but I suppose it's of that sort?

21   A.   We would call it advertising, yes.

22   Q.   You would call it advertising?

23   A.   Yes. You see it on the television, "Give blood".

24   Q.   Promotion, perhaps. I don't know.

25                 Then on to the following page, "Component therapy".

1           So making use of the different elements as far as  
2           possible. Splitting the blood up. I think we can  
3           understand that too. You say you began to provide red  
4           cells for transfusion in 1960. And you are right, we  
5           have heard evidence from both Professor Turner and  
6           Dr Norfolk about the most economic ways of using  
7           a donation of blood, particularly this emphasis on only  
8           using red cells.

9           It says:

10           "Eventually SNBTS actually ceased to supply whole  
11           blood routinely."

12           So that became the default, that people were just  
13           given red cells?

14    A. That's my understanding. I think it is important to  
15           appreciate the effort that was required to achieve this,  
16           because you were trying to educate doctors in every  
17           hospital in Scotland virtually to change their clinical  
18           practice, and I don't think that was at all easy.

19    Q. No. I'm sure. Then on to the next page, you go into  
20           this topic of producing enough albumin. So when enough  
21           albumin was being produced at PFC, it was possible to  
22           stop freeze-drying plasma in the West and send the  
23           plasma to PFC instead?

24    A. That's correct, and just to finish the equation: what  
25           was happening at this time was while PFC was being

1 constructed, outdated plasma was being stored, frozen,  
2 so that there was a stockpile of plasma. So once PFC  
3 was functioning, we could process the stockpile of  
4 outdated plasma to albumin and that would then release  
5 plasma that was fresh-frozen that had otherwise been  
6 used to make freeze-dried plasma in Glasgow.

7 Q. Right. So really another example of the most economical  
8 use of the different bits?

9 A. Yes.

10 Q. Yes. Just at the end of that section you have talked  
11 about the use of a freeze-drying plant at Glasgow for  
12 the preparation of freeze-dried cryoprecipitate, but  
13 that that plant was closed. Just to look at a couple of  
14 references we have to this part of the story,  
15 SNB0015064. I think there is a reference to the second  
16 page. This is a meeting of the Haemophilia and Blood  
17 Transfusion Working Group on 4 March 1981. It says:

18 "The production of freeze-dried cryoprecipitate."

19 We have looked at this before as well. So it does  
20 look as though, at least in March 1981, it was thought  
21 that this might have some future as product. If we look  
22 at [\[SNB0015160\]](#), at the third page, please, which is  
23 SNB0015162. Right at the bottom of the page, please,  
24 there is a reference to freeze-dried cryoprecipitate:

25 "There has been a successful clinical trial in the



1 west. Notwithstanding this work, it had been decided to  
2 abandon production of freeze-dried cryoprecipitate in  
3 the meantime, having regard to the closure of the plasma  
4 freeze-drying plant at Law and the cost of meeting the  
5 standards demanded by the medicines inspectorate."

6 I suppose it is essentially the other way round,  
7 that the cost of meeting the standards demanded by the  
8 Medicines Inspectorate had contributed to the closure?

9 A. I would say that was the overwhelming point. It is not  
10 just the cost; it was actually more than that. It was  
11 actually working out if it was possible to meet those  
12 demands at all with this type of product. I was  
13 familiar with this because I was present when the  
14 medicines inspectors inspected the plant at Glasgow. So  
15 I understood what their concerns were. It wasn't just  
16 the plant, which was elderly, it was the notion of how  
17 can this particular type of product comply with what  
18 they regard as good manufacturing practice. Because it  
19 wasn't what we would call the aseptic product; it  
20 couldn't be filtered to remove bacteria. It couldn't be  
21 sampled easily with the number of samples I have  
22 mentioned already. 25 samples from a batch; you  
23 couldn't do that with cryoprecipitate. So it didn't  
24 comply with any of these aspects that were regarded as  
25 important to good manufacturing practice.

1 Q. So, notwithstanding that there may have been  
2 a successful clinical trial, there were all these  
3 problems earlier in the sequence which were almost  
4 impossible to overcome?

5 A. I think if doctors had come back and said, "This is  
6 a brilliant product, we must have it, it is absolutely  
7 essential," then I think the medicines inspectors might  
8 have reviewed their position but that didn't happen.

9 THE CHAIRMAN: I would like to be sure I do understand this.

10 There are a number of different strands that come  
11 out of the documents. One is that it might have been  
12 useful for some particular clinical applications and  
13 there was discussion of that, but this seems simply to  
14 have disappeared into the background. The other is that  
15 I think the predominant feature that one sees in the  
16 documents is the cost of meeting the medicines  
17 inspectors' criticisms of the Law plant. But you were  
18 there and you say that there were many more fundamental  
19 issues really, the inability fully and properly to test  
20 the material. Why was that?

21 A. That is because when you have a batch of  
22 a pharmaceutical product, you have to carry out testing  
23 to ensure that it is uniform and a specified number of  
24 samples must be taken, and the size of the batch of  
25 freeze-dried cryo wasn't big enough to allow that sample

1 to be met.

2 THE CHAIRMAN: There were basically five donations that they  
3 were working on.

4 A. That's correct. There wasn't enough in the batch to  
5 meet all the sampling requirement, never mind treat the  
6 patient. So you are in between the pharmaceutical  
7 product and what was a blood component, and it was  
8 trying to find the balance. And because it was being  
9 manufactured and freeze-dried in a what was  
10 a manufacturing environment, the inspectors saw it more  
11 as a pharmaceutical product than a blood product that  
12 you would get at the blood bank. And that might have  
13 been a debate that could have carried on if there had  
14 been a huge demand for the product, but it didn't, it  
15 ended there, and of course, the financial cost of  
16 building a new freeze-drying plant was not small.

17 THE CHAIRMAN: So it really was a combination of factors and  
18 the debate really was brought to an end rather than  
19 fought out.

20 A. I would say so, yes.

21 THE CHAIRMAN: I think that's very interesting about the  
22 final stages in Law's history, at least on this topic.

23 MS DUNLOP: Yes. We are still about how to increase  
24 fresh-frozen plasma, Dr Foster. Can we go back to your  
25 paper at page 32, which is 1156. Thank you.

1           You had been working to a time limit of six hours,  
2           which you say is a significant constraint especially for  
3           donations collected in the evening or at locations far  
4           removed from the processing laboratories. You looked  
5           into whether plasma frozen within 18 hours of donation  
6           would be suitable, if there was any possibility of  
7           relaxing the time constraint but there was a yield  
8           penalty. You say:

9           "18-hour fresh-frozen plasma was introduced  
10          routinely in 1975 and enabled the supply of plasma to be  
11          increased by about 30 per cent."

12          We can understand the thinking there. Then:

13          "Optimal additive solution."

14          As I understand that, that was to reduce the amount  
15          of plasma that had to be retained in a packet of red  
16          cells, as it were?

17   A. That's correct.

18   Q. To make the red cells usable?

19   A. That's correct, yes.

20   Q. So you put something else in with the red cells and that  
21          increases the amount of plasma you can take out?

22   A. I think the motivation was originally to benefit the red  
23          cells but the knock-on effect was that you could recover  
24          more plasma.

25   Q. Onto the next page, we come to plasmapheresis. I should

1 ask you at the start, Dr Foster, why was plasmapheresis  
2 not used in the United Kingdom at this time? We seem to  
3 have been very slow --

4 A. I'm perhaps not the best person to ask because  
5 collecting plasma wasn't the area that I was working in.

6 Q. No.

7 A. But I think at first there was certainly a reliance on  
8 the normal blood donor. I think if you go back to  
9 General Jeffrey's paper from 1976, he notes the  
10 importance of plasmapheresis and this might be needed,  
11 but he points out that it is expensive and  
12 time-consuming, but he doesn't dismiss that as  
13 a possibility. He does identify it. And I think  
14 certainly by the late 1970s, early 1980s, that was being  
15 explored and we were doing studies in Scotland.  
16 Certainly at PFC we were studying plasma collected by  
17 plasmapheresis in my department to establish that it  
18 would be appropriate to manufacture Factor VIII from it,  
19 but the bottom line really is that it is an expensive  
20 technique and it requires funding and that funding  
21 wasn't made available until 1990.

22 THE CHAIRMAN: This is where I would like to fill in  
23 a little bit of the history.

24 I have a note of a meeting of the SNBTS directors on  
25 17 March 1981, when Dr Urbaniak reported on the work of

1 the Jenkins working party, which was trying to put  
2 together a code of practice for plasmapheresis. Did you  
3 know about that?

4 A. I don't know about the details but I did know that  
5 Aberdeen did some work to collect plasma by  
6 plasmapheresis, which they sent to us to investigate to  
7 see if it was appropriate. Similarly, in Leeds in  
8 England they were doing something similar and they sent  
9 us the plasma to explore but I think it was after that  
10 that the funding wasn't available.

11 THE CHAIRMAN: The reference to that minute is [\[SNB0022629\]](#)  
12 or 26289. I don't think we need it, it is just to get  
13 its place. The next reference I have after that,  
14 I think, does take us into a wider sort of context, but  
15 I also have a note from March 1981 of the SNBTS  
16 directors talking about it and proposing to send a team  
17 to Belgium, which is what I mentioned earlier.

18 A. Yes.

19 THE CHAIRMAN: That is [\[SGF0010327\]](#). A group of SNBTS staff  
20 were to go to Belgium, where there was an extensive  
21 programme of plasmapheresis at the time, but you don't  
22 remember that, or you weren't involved?

23 A. I wasn't involved in that. I wasn't a member of that  
24 committee but I have seen documents since and a team  
25 went and they did write a report. I think

1 Brian McClelland was probably the author of the report  
2 and I think that probably did lead Professor Cash to  
3 make bids for plasmapheresis which weren't funded.

4 THE CHAIRMAN: That's where it comes to an end really at  
5 that stage. The lack of funding put an end to that  
6 project.

7 A. That would be my explanation but you need to check  
8 that --

9 THE CHAIRMAN: We will ask Professor Cash. I think that is  
10 the story, Ms Dunlop, but clearly we want to make sure  
11 that we get it rounded off since plasmapheresis could  
12 have been quite important had it been taken off.

13 A. It could have provided considerably more plasma, yes.

14 MS DUNLOP: In your paper, Dr Foster, you take us back to  
15 the generous provisions in the United States of America.  
16 60 litres per annum per donor. And a maximum of about  
17 12 litres per donor per annum in the UK, but in the  
18 period in which we are principally interested, which is  
19 late 1970s, early 1980s, none at all in practice.

20 A. Not by plasmapheresis, no. Not for fresh-frozen plasma.

21 Q. And you have indeed quoted in your paper that section  
22 from Major -- I'm calling him Colonel Jeffrey?

23 A. Major General.

24 THE CHAIRMAN: I think if there is one word it has to be  
25 General rather than Major.

1 MS DUNLOP: Major General.

2 THE CHAIRMAN: He is a Major General. A very model one, I'm  
3 sure.

4 MS DUNLOP: Yes, General Jeffrey in 1976. Time-consuming  
5 for both donor and operator and involves expensive  
6 equipment. On to the next page, you say:

7 "Plasmapheresis. To collect normal plasma wasn't  
8 available to SNBTS until 1990."

9 A number of other avenues were explored to obtain  
10 additional plasma, and there is the Kansas proposal,  
11 1979. Mr Watt thought he could import plasma from  
12 unpaid donors in Kansas. It was not used for  
13 Factor VIII concentrate manufacture but by putting it in  
14 at another stage of your work, you were able to free up  
15 plasma to go towards concentrate manufacture, as  
16 I understand it?

17 A. One of the difficulties throughout this period was  
18 actually getting enough plasma to do research because  
19 there was so much demand by the patients, and obviously  
20 you wanted the plasma to go to the patient, the products  
21 to the patients. So getting an alternative supply of  
22 plasma that could be used for research was quite helpful  
23 at that time.

24 Q. Right. So at that point you weren't competing with  
25 those who were actually manufacturing product directly



1 to get plasma for research?

2 A. Well, it was up to Mr Watt to allocate resources to the  
3 best of his judgment, but clearly if there was an  
4 enormous pressure to produce the product, then the  
5 plasma would go in that direction, and we actually had  
6 to encourage our staff to give plasma by plasmapheresis  
7 to provide material for research, and we had quite  
8 a number of staff signed up for that.

9 Q. So the staff at PFC themselves?

10 A. That's correct.

11 Q. So they were the exception to the proposition that  
12 plasmapheresis wasn't being used in Scotland?

13 A. That's actually a good point, yes. I had to do that  
14 myself to show a good example.

15 Q. Yes. Thank you.

16 The second illustration you give us of another  
17 effort that was made was to try to squeeze more  
18 Factor VIII from the cryo but that wasn't so successful  
19 because the potency of trial batches was too low?

20 A. That's what transpired, yes.

21 Q. Yes. Then thaw siphon technique is the third one.

22 Basically, as I understand this, this is to get more  
23 Factor VIII in the cryoprecipitate, which was going for  
24 cryoprecipitate, because then less plasma would be  
25 required to make cryoprecipitate?

1 A. Yes, you made the point earlier that at some points one  
2 has to decide, does the plasma go to cryoprecipitate or  
3 does it go to PFC, and if you have a higher yield in the  
4 cryoprecipitate at the blood bank, then you can provide  
5 more plasma to PFC.

6 Q. Yes, I think we understand that, thank you. Then you  
7 say:

8 "As a result of these strategies, the amount of FFP  
9 supplied by SNBTS increased greatly from 1974/1975."

10 You have put that in a table for us and we can see  
11 for ourselves that indeed from 1974 to 1975, where you  
12 had 1,934 kilogrammes per million people, in 1997 to  
13 1998 you had 13,019 kilogrammes per million people.

14 So on any view, a significant and steady increase.  
15 It is also interesting to look at this table and see  
16 that breakdown, the amount of fresh-frozen plasma that  
17 was going for the preparation of cryoprecipitate and the  
18 amount that was going to concentrate. And we can see  
19 the cryo is declining. Then there are three years,  
20 Beginning 1977, 1978 and 1979 where it seems steadier.  
21 Indeed, there is a slight increase in 1978/79, but then  
22 after the year 1979/80, a decline again. One or two  
23 blips but the amount going to concentrate is steadily  
24 increasing. Do you remember Dr Howard Davies?

25 A. I never met him, no.

1 Q. Was it well-known in Edinburgh in the 1970s that he  
2 didn't want to use commercial concentrates?

3 A. I didn't know that.

4 Q. Right. In your commentary, if we could go down, please,  
5 you say:

6 "The data demonstrate both the magnitude of the year  
7 on year increase and the increasing emphasis on the  
8 preparation of Factor VIII instead of cryoprecipitate."

9 Then on the next page. Although the increases in  
10 the amount of fresh-frozen plasma to PFC fluctuated,  
11 there was always an annual increase in the amount of FFP  
12 to PFC, well, until 1984/85, we can see there is  
13 a decline, but up to the end of 1984, including some  
14 pretty significant year on year increases in the amount  
15 of FFP going to PFC. You explain in your bullets under  
16 the table why some particularly significant increases  
17 occurred.

18 Then on to section 5, SNBTS manufacturing  
19 capability. Some more historical material, Dr Foster,  
20 blood products unit between 1950 and 1974. This is the  
21 one at the Royal Infirmary actually in the basement. Is  
22 that right?

23 A. Yes, it was in the same block as the  
24 regional transfusion centre, and the  
25 regional transfusion centre was on the ground floor and

1 the blood products production unit was in the basement.

2 Q. Right.

3 A. Next door was the haematology department.

4 Q. And you say:

5 "The first plasma products prepared there were

6 immunoglobulin for the prevention of measles and

7 Cohn Fraction I."

8 THE CHAIRMAN: Could I ask one question? There is something

9 I'm not at all clear about and that is whether the Cohn

10 fractionation was limited to Edinburgh or whether it

11 happened in other transfusion centres. Can you help me?

12 A. Cohn fractionation didn't happen in transfusion centres,

13 it only happened in what we would call fractionation

14 centres, and there were only three of those in the UK,

15 one at Elstree, one at Oxford and one at Edinburgh. And

16 Oxford only focused on coagulation factors.

17 THE CHAIRMAN: So what was happening throughout the rest of

18 Scotland until PFC was established at Liberton? What

19 was happening locally?

20 A. In what respect?

21 THE CHAIRMAN: In respect of the preparation of any sort of

22 therapeutic material.

23 A. Blood products would be prepared at the regional

24 transfusion centres and then this was the national unit.

25 Edinburgh was the national unit for plasma products.

1 THE CHAIRMAN: So what would they do at Aberdeen, for  
2 example?

3 A. They would obtain material from the national unit in  
4 Edinburgh.

5 THE CHAIRMAN: Right.

6 A. This Cohn Fraction I that was manufactured at this time  
7 actually was distributed as far south as Newcastle?

8 THE CHAIRMAN: Did everybody make cryoprecipitate?

9 A. From 1966 onwards, yes.

10 THE CHAIRMAN: Thank you.

11 MS DUNLOP: Just to go back, and this is, I think, quite  
12 basic, but just so that we understand, at the beginning  
13 of your evidence we talked about cryoprecipitate as  
14 a starting material that can go and be used in the  
15 treatment of haemophilia as cryoprecipitate, or it can  
16 be used as the starting material for the production of  
17 Factor VIII concentrate at PFC. In that process, as we  
18 understand it to have been occurring, particularly in  
19 the early 1980s, where, if at all, does Cohn  
20 fractionation feature?

21 A. Cohn fractionation is the procedure devised by  
22 Edwin Cohn, which I don't need to go into the chemistry  
23 of, but at PFC, once we had removed the cryoprecipitate  
24 from the plasma, we would then apply the Cohn  
25 fractionation process.

1 Q. Right. So when we spoke about the freezing and then  
2 taking the gloopy stuff or the gungy stuff from the  
3 cryoprecipitate, at that point you used Cohn  
4 fractionation in obtaining what will eventually become  
5 the powder which is going to be the freeze-dried  
6 Factor VIII. Is that right?

7 A. No.

8 Q. No? Sorry.

9 A. The cryoprecipitate is then processed to be an  
10 intermediate purity product that comes to Factor VIII as  
11 a concentrate; it doesn't involve Cohn fractionation at  
12 all.

13 Q. That's why I'm asking actually, because I think it is  
14 possible to get distracted by Cohn fractionation.

15 A. It is the liquid that is left after the cryoprecipitate  
16 has been removed. We called it cryo-depleted plasma, if  
17 you like. That then is subjected to Cohn fractionation,  
18 and the objective of Cohn fractionation is to produce  
19 immunoglobulin and albumin.

20 Q. Yes. So in fact, in the whole of the process, going  
21 from cryoprecipitate to Factor VIII, you don't need Cohn  
22 fractionation to get the Factor VIII?

23 A. No. You only need that to process the residual plasma  
24 to obtain albumin and immunoglobulin.

25 Q. Thank you. Thanks. That was my impression but just so

1           that we are clear.

2   THE CHAIRMAN:  It doesn't clarify everything for me since

3           Fraction I contained Factor VIII, as I understand it.

4   A.  That's correct.  And the early concentrate was made from

5           Fraction I --

6   THE CHAIRMAN:  Indeed, and I think history is part of the

7           problem here, that we do have to know what was happening

8           over particular periods of time, rather than the

9           generality.

10  A.  When cryoprecipitate came along, that was a better

11           starting material for Factor VIII production than

12           Fraction I.  So Fraction I was only used to prepare

13           fibrinogen after the cryoprecipitate had been removed.

14  THE CHAIRMAN:  When we hear about antihaemophilic globulin

15           in the early days, what was that?

16  A.  Factor VIII.

17  THE CHAIRMAN:  And that came from Cohn Fraction I?

18  A.  Yes.  That was in Cohn Fraction I.  Today we would call

19           it Factor VIII activity.

20  MS DUNLOP:  Yes.  I think it's possible, Dr Foster, as we

21           said at the start, for us to misunderstand something

22           which is absolutely basic for you but it isn't for us.

23  THE CHAIRMAN:  You must assume that nothing is basic for us.

24  MS DUNLOP:  Yes.

25           Having told us about the era before the opening of

1 PFC at Liberton, you then go on in 5.1.4 to tell us  
2 about the opening of PFC at Liberton in 1975, and we  
3 know from our background reading that there was quite  
4 a debate about whether PFC would be used to process  
5 English plasma, and that that in the end never happened.  
6 In fact, from your article, which I think we will go to  
7 later on today, you think that in retrospect that was  
8 very unfortunate for PFC. Is that correct?

9 A. It was certainly John Watt's view that PFC -- John Watt  
10 was advising a number of countries and he understood  
11 that the fractionation process was very expensive and in  
12 order to afford it, if you like, you had to have  
13 a certain population to sustain that infrastructure that  
14 was required, and Scotland, he thought, was too small  
15 and really he thought it needed a bigger population to  
16 keep the facility working economically. And of course,  
17 that kind of analysis was delayed slightly because the  
18 demand became much greater than he had imagined. So  
19 I think the economics weren't quite what he imagined it  
20 would be but ultimately PFC was judged to be not  
21 economic for Scotland alone.

22 Q. You say that the DHSS decided not to use PFC for the  
23 fractionation of plasma for England and Wales and this  
24 was judged wrongly to be more expensive than the  
25 construction of a larger and newer facility at the BPL.



1 We are not investigating in any detail what happened in  
2 England and Wales, but really in the early 1980s there  
3 was quite a saga about the construction works at BPL,  
4 was there not?

5 A. Well, BPL facility was inspected, I think, around about  
6 1979 and the outcome of that was that they really needed  
7 a new facility to comply with the standards that were  
8 needed and also because the demand for the product had  
9 exceeded their capacity. So there were two reasons for  
10 building a new facility and the discussion then was what  
11 size should it be built to. Should it be built to  
12 handle the whole of England and Wales and send half to  
13 Scotland or should they build a large plant, and the  
14 decision ultimately was to build the large plant for the  
15 whole of England and Wales and not to send plasma to  
16 Scotland, and that was justified on some costings that  
17 I think, looking at now, could be seen to be quite  
18 wrong.

19 Q. Given what was destined to unfold, in the shape of the  
20 AIDS crisis, it was not a good time to realise that you  
21 needed a new factory. Or is that not fair?

22 A. I think a new factory was required but I think if people  
23 had known of the problems in the future, then they might  
24 have taken a faster track to getting that off the ground  
25 and part of that would have been to make better use of

1 the Scottish facility.

2 THE CHAIRMAN: Dr Foster, I would have very much liked to  
3 ask John Watt about the period when processing for  
4 England seems simply to have disappeared into the sand.  
5 I know that some plasma did come from England and was  
6 held in store for quite a period of time, but it wasn't  
7 processed because I think Mr Watt wasn't satisfied about  
8 the procedural arrangements that would be made for its  
9 distribution in England. I rather think he wanted to be  
10 sure that the product went back to the plasma source.  
11 Do you have any feel for the debate that was going on  
12 over this time?

13 A. Yes, I have a reasonable understanding of it, partly  
14 because of documents that have been released more  
15 recently that tell me the story because I didn't at the  
16 time understand it all. But really, when PFC was being  
17 planned, there were discussions with different  
18 departments and it was agreed that PFC would process  
19 plasma from the north of England as well as Scotland,  
20 and that was actually written into my job description  
21 I have to say when I began work there.

22 Once PFC was constructed, John was quite keen to  
23 begin this process of handling English plasma but to do  
24 that, we needed more equipment because we had only been  
25 funded to handle Scotland and we also needed new

1 staffing arrangements to handle this extra plasma. And  
2 at that time this was for albumin, it wasn't for  
3 Factor VIII and really the staffing arrangements that  
4 were needed failed to be achieved because, although  
5 a system for staffing was negotiated and was approved in  
6 Scotland, it wasn't accepted by the  
7 Department of Employment because it was judged to  
8 contravene the government's incomes policy at the  
9 time -- not incomes policy. The Callaghan government  
10 had a pay policy and it was judged to contravene that.

11 THE CHAIRMAN: The overtime couldn't be worked?

12 A. It was more of a shift system. It was seen to  
13 contravene the government's policy and then the issue  
14 came back around about 1980/1981 when there was this  
15 question about what they were going to do to rebuild  
16 BPL, and we did receive plasma from England and we did  
17 process it in an experiment to show that we could  
18 actually handle that quantity and that from our point of  
19 view that experiment was quite successful.

20 So we had actually proved that we could handle it if  
21 we had the proper staffing arrangements but then this  
22 analysis that I mentioned earlier, the economic  
23 analysis, the costings that were carried out, that  
24 showed that it would be cheaper to build BPL at the  
25 larger size, took precedence and we can see that that

1           was incorrect.

2   THE CHAIRMAN:  It turned out to be incorrect but we can  
3           understand what was going on, thanks to the explanation.

4           Thank you very much.

5   MS DUNLOP:  You also mention on the following page,  
6           Dr Foster, page 38, that the design of PFC was  
7           essentially completed in 1970 and then government  
8           guidance on the construction of and operation of the  
9           facilities for the manufacture of pharmaceuticals in the  
10          UK was first published in 1971.  Certainly when one  
11          reads that, it sounds the wrong way round.  You would  
12          presumably, in an ideal world, choose to have the  
13          government guidance and then you would design your  
14          building accordingly.

15   A.  The government guidance followed the Medicines Act that  
16          was introduced in 1968, and the creation of Medicines  
17          Division and Medicines Inspectorate and they produced  
18          guidelines.  And they weren't dealing with us  
19          specifically, they were looking at the whole of the  
20          pharmaceutical sector in the UK.

21                 The decision to build a plant in Scotland had been  
22          taken before any of that started and didn't wait to see  
23          what was going to happen.  But the design was drawn up  
24          to what was thought to be best practice at the time,  
25          based on World Health guidelines and what other

1 manufacturers were doing around the world. And we can  
2 only see now, looking back, that these things were  
3 happening in parallel: the plant was constructed and in  
4 parallel with that the inspectorate was getting going  
5 and beginning to look at the standards and change the  
6 standards in the UK. But I think the same thing  
7 affected BPL because they had a major reconstruction at  
8 this time and they were really in the same position.

9 Q. No doubt that sequence of events led to what you go on  
10 to discuss, that PFC later had to carry out  
11 modifications to comply with Medicines Control Agency  
12 guidance. You say you also carried out work to increase  
13 the capability of the centre. So an extension in 1982  
14 and 1983 and another extension in the early 1990s?

15 A. I think by the time PFC opened, John Watt was well aware  
16 that standards were moving and the earlier designs were  
17 becoming out of date. But to justify funding to make  
18 these improvements, he needed a medicines inspection in  
19 order to have something in writing to say this is what  
20 is required. And I know from personal experience he was  
21 nagging the inspectorate to come and visit PFC, really  
22 from 1975 onwards, but they had other priorities. So  
23 they didn't get to us until about 1980. By that time  
24 a cumulative number of things had to be done to make the  
25 improvements needed that had been accumulating over that

1 ten-year period, and that all kind of focused in on the  
2 period in the early 1980s.

3 Q. Right. Can we move on, please, to the next page at the  
4 top. You say that PFC closed in 2008. And bearing in  
5 mind that this is all still within section 5, which is  
6 dealing with manufacturing capability, you move on to  
7 talk about the regional blood transfusion centres and  
8 I think we all know where these were based. The Glasgow  
9 one from 2001, I think has been based at Gartnavel.  
10 Yes, you do go on to say that. And you have then given  
11 us, in table 8, a breakdown of the fresh-frozen plasma  
12 according to transfusion centre. Unsurprisingly about  
13 80 per cent of the FFP was provided by Edinburgh and  
14 Glasgow combined.

15 We can see really not a lot of change between 1974  
16 to 1975 and 1983 to 1984; very similar sorts of  
17 percentages.

18 Then on to the following page. You deal with the  
19 centres individually. Law Hospital, you say, which  
20 opened in 1939, according to some reading that I have  
21 done, at that time was anticipated to have a ten to  
22 15-year lifespan but plainly it lasted longer than that.  
23 Large number of pre-fabricated buildings in an open  
24 rural location.

25 Dr Foster, the one in the West of Scotland, Law,

1           rather stands out from the other four. If you think of  
2           the Aberdeen one being based at Aberdeen Royal Infirmary  
3           at Foresterhill, Dundee based at Nine Wells, Edinburgh  
4           based at the Royal Infirmary in Edinburgh and Inverness  
5           based at Raigmore, the centre for Glasgow was rather out  
6           on a limb, was it not?

7    A. My understanding was that Law Hospital was built in  
8           Carluke because Glasgow was thought to be the focus for  
9           bombing during World War II and they wanted it out of  
10          the city centre and it remained there. As you say, it  
11          took a long time to replace it.

12   Q. I don't suppose you know why a decision was taken to put  
13          the regional transfusion centre there as well?

14   A. I don't know the answer to that, no.

15   Q. There must have been practical inconvenience in its  
16          being situated so far from Glasgow city centre. It is  
17          not quite half way to Edinburgh but it is a decent  
18          distance from Glasgow city centre?

19   A. I think you need to put that question to Dr Mitchell.

20   Q. I don't suppose he decided to build it there either.

21                 Right and you have charted for us the various moves  
22          that took place in Edinburgh as well. Then in  
23          section 5.3:

24                 "Know-how for the preparation of SNBTS coagulation  
25          factor concentrates."

1           Just at this point, Dr Foster, I wanted to share  
2           your article that you have given us. We have some hard  
3           copies. I'm hoping that people have hard copies of  
4           this, sir. I can make more available if people are  
5           wanting to take one away and we will obviously put it  
6           into court book. It is just that I have only seen it  
7           since yesterday and it's an article by Dr Foster from  
8           the SNBTS Blood Letter, is that what it's called, the  
9           publication?

10        A. That's correct, it's an external publication within  
11        SNBTS.

12        Q. From the spring of 2008, pages 21 to 23, and you no  
13        doubt wrote this because of the closure of PFC. Was  
14        that the stimulus?

15        A. It was, yes.

16        Q. Yes. We can see for ourselves the origin of PFC: The  
17        underground site at the Royal Infirmary, the move to  
18        plasma fractionation premises at the Royal Infirmary,  
19        opened in September 1950, Dr Robert Cumming and  
20        Dr Drummond Ellis, and then between 1951 and 1974  
21        Dr Ellis went to the United States to study plasma  
22        fractionation at the laboratory of Dr Edwin Cohn and, no  
23        doubt influenced by that, came back and planned the  
24        installation and designed much of the equipment to  
25        produce Scotland's first fractionated plasma product.



1           That's the immunoglobulin for the prevention of measles  
2           infection, 1952, and then an early version of  
3           Factor VIII, Cohn Fraction I.

4           Sir, this is maybe where the four flasks of AHG come  
5           in?

6   A.   If you look at the photograph on the first page, the top  
7           right-hand photograph, there are a number of bottles.  
8           The top right-hand bottle, which actually has a blue  
9           cover that you can't see in your copy, is actually the  
10          antihaemophilic fraction that we call Cohn Fraction I.  
11          I would imagine that was the product that the  
12          Reverend Black received.

13   Q.   Right. A picture is worth a thousand words, Dr Foster?

14   THE CHAIRMAN: Only if you can see it.

15   MS DUNLOP: It's a great deal better than no picture at all.

16          What are we looking at? Are we looking at a bottle  
17          of white --

18   A.   It's freeze-dried, yes.

19   THE CHAIRMAN: -- powder? Right. So you don't know where  
20          flasks would come into it. It might just have been done  
21          in flasks rather than --

22   A.   It was manufactured in -- I would say it was a jar, if  
23          you like. It held about 3 litres of material, so  
24          I would guess it was about 12 donations of plasma in the  
25          pool.

1 Q. Then you say:  
2 "Demand continued to increase."  
3 I think we know about that.  
4 Mr Watt came. Mr Watt had previously worked on the  
5 fractionation of animal plasma at the Royal (Dick)  
6 Veterinary College, which I think helps to explain what  
7 might have been slight puzzlement on our part as to his  
8 background in veterinary medicine. But it was really  
9 his background in fractionation that was important,  
10 I take it?  
11 A. Yes, that's correct.  
12 Q. Then you mention the close collaboration with  
13 Dr Alan Johnson. Then, 1975 to 1983, 35 staff moved  
14 from the Royal Infirmary and a further 90 were appointed  
15 to operate the new centre, and you mention Dr Jim Smith,  
16 who we will be hearing from in September.  
17 Then your reference to the design being to  
18 accommodate plasma from the north of England, but  
19 obviously we know that that didn't happen.  
20 Then, on to the next page, you say:  
21 "The success of Factor VIII concentrate led to  
22 demand greatly exceeding all projections."  
23 And Mr Watt's departure at the end of 1983.  
24 Then, 1984 to 1994, you discuss heat treatment.  
25 But thank you for providing this, Dr Foster. It

1           seems a useful story of the history of matters, sir, and  
2           that's why we want to put it into court book.

3   THE CHAIRMAN:  Yes, I think it's very useful indeed.

4           Glasgow didn't try the Cohn fractionation process at  
5           all, did it?

6   A.  I don't think so, no.

7   THE CHAIRMAN:  No.

8   A.  It needed special facilities and I think Edinburgh was  
9           chosen as the place.

10  THE CHAIRMAN:  Yes.  And Glasgow clung on somewhat  
11           tenaciously to cryoprecipitate for a period after that?

12  A.  Yes, that's true, yes.  I think the decision to site  
13           fractionation in Edinburgh actually came from  
14           Dr Robert Cumming, who was the Edinburgh transfusion  
15           regional director, who joined, I think, about 1948, and  
16           he perhaps had the vision to see what was needed and  
17           made the progress in Edinburgh.

18  MS DUNLOP:  Just to mention this, Dr Foster, because it's  
19           another interesting historical document which is in fact  
20           referred to in the preliminary report, but we have  
21           "Fifty years of an organised Blood Transfusion Service  
22           in Scotland", which is [\[SNB0101836\]](#), and a bit more  
23           information about some of those involved.

24           Particularly, if we read through it, we can see that  
25           from page 4 onwards there is the section headed up "The

1 separation of plasma". You, presumably, are very  
2 familiar with this piece as well, Dr Foster, are you?  
3 A. I have read some articles by Girdwood. I think I have  
4 glanced at this one, yes.  
5 Q. Mention of Dr Cumming on page 5.  
6 A. This looks like the draft was published eventually.  
7 Q. Yes. It was published, I think, in the Scottish Medical  
8 Journal?  
9 A. That's right.  
10 Q. Yes, you are right, this is not a copy of the text as  
11 published.  
12 More information about Dr Cumming, who had been  
13 a Japanese prisoner of war, and some more discussion of  
14 the products on to the next page.  
15 Plasmapheresis, although not suggesting that that  
16 was actually happening.  
17 Then some discussion of the different centres around  
18 Scotland.  
19 So your section on know-how, to which we need to  
20 return, Dr Foster. Section 5.3 on page 40 of  
21 [\[PEN0131125\]](#). You refer to a chance meeting in 1966 in  
22 Australia between Mr Watt and Dr Alan Johnson, and his  
23 is a name we see quite frequently over the ensuing  
24 decades in fact. There was obviously a connection  
25 established there which lasted some time. Is that

1 right?

2 A. Yes, it lasted really for many, many years. I became  
3 good friends with Dr Johnson. Really from the 1950s and  
4 1960s he became probably one of the world's leading  
5 experts in the development of Factor VIII concentrate  
6 and it was really out of his work in part that the  
7 concentrates actually were ultimately developed.

8 Q. And that's why you named one of them "NY", wasn't it?

9 A. Exactly, because we used his method and his advice.  
10 I don't know who came up with the term "NY" but it  
11 reflects New York and that's where he was based. So it  
12 was an acknowledgment of his contribution.

13 Q. Move on to the next page. You explain that it was  
14 really a global network of contacts, presumably with  
15 a view to sharing information about R and D. That must  
16 be difficult at times, Dr Foster, because -- we have  
17 seen your patent applications listed. We may come on to  
18 this far more in the autumn, but there must be a balance  
19 to be struck between sharing information and not giving  
20 away some development that you alone have perhaps  
21 identified?

22 A. I think, certainly in the not for profit sector, I never  
23 found any impediment. We would reasonably get to know  
24 who was doing what in which place, and particularly BPL,  
25 and if you had a question or a comment, we could phone

1           them up and they would talk to us and sometimes they  
2           might say, "I'm not supposed to speak to you but I'm  
3           going to talk to you anyway."

4           So there was quite a lot of exchange, certainly at  
5           my level, without any difficulty whatsoever. There  
6           might have been the occasional thing where there was  
7           a patent application pending, or some agreement with  
8           some other third party, that precluded discussions, that  
9           required confidentiality, but that was really quite  
10          rare.

11        Q. You now take us to section 6, which is "Blood products  
12          for the treatment of haemophilia", and you give us  
13          a introduction, a lot of the content of which we are,  
14          I think at the moment, reasonably familiar, thank you.

15          On to the next page. You do mention purity and  
16          potency. Can I ask you to have a look at [\[PEN0150445\]](#)?  
17          This is Professor Ludlam's statement. Can we go to  
18          page 13 of this, please? Sorry, I'm not sure that we  
19          are at the right section. Can we go on to the next  
20          page, please? Sorry, I have forgotten my hard copy,  
21          sir. There is a section on purity and potency in this.  
22          Can we scroll through until we come to it? I think it's  
23          suggested in the index it's page 13 but it doesn't look  
24          to be.

25          Yes, here we are: "Clotting factor concentrate,

1           purity and potency".

2           I think I should ask you, Dr Foster, because we have  
3           found this slightly challenging: do you agree with the  
4           way Professor Ludlam has set it out? Don't worry, I'm  
5           sure he would defer to you, but is this a reasonable  
6           explanation?

7    A. I think I might have put it slightly differently.  
8           I tend to refer to a textbook from the same period,  
9           where there was a chapter written by Dr Smith, where he  
10          gives his definition, and for me it's slightly different  
11          but I don't know that we need to get into details of  
12          decimal points.

13          But, generally speaking, the products that we were  
14          manufacturing -- and I think this is said later on in  
15          the document -- what we called "intermediate purity  
16          concentrate" -- and that was the general term that was  
17          used -- was of the order of half a unit per milligramme  
18          in terms of its specific activity, and the main issue --  
19          and it leads into potency and dose size and everything  
20          else -- really comes back to something we discussed  
21          earlier, which is this source of plasma and the way that  
22          is provided.

23          We have seen that in Scotland we had blood from  
24          ordinary blood donors, who would donate maybe half  
25          a litre of plasma a year; we have seen that in the

1 United States they have what from our perspective looked  
2 like a reservoir of plasma available. In order to  
3 achieve the further purification that did exist with the  
4 commercial products, you had to carry out further  
5 processing and that had a yield penalty. There were  
6 a number of reasons for that, which I can go into if you  
7 like, but ultimately, if we had done that, we would have  
8 either needed more plasma or we would have reduced our  
9 output and because we didn't have enough plasma, the  
10 bottom line is we would have reduced our output, at  
11 a time when we couldn't make enough.

12 The commercial companies, on the other hand, had  
13 this large reservoir of plasma. So, for them, they  
14 could accommodate a reduction in yield without any great  
15 difficulty and produce what was a more purified  
16 material. To give you a feel for it, our product would  
17 be of a purity of about 0.5 or slightly less units per  
18 milligramme of protein and the commercial products might  
19 be up to 1 or even 1.5 units per milligramme of protein.  
20 So it was maybe a doubling or tripling in terms of  
21 specific activity. But the reason for that was that  
22 they could afford to do that because they had access to  
23 this plasma. If we had as much plasma as that, there  
24 would have been no difficulty in doing that.

25 There were a number of implications that that has



1 because, in terms of potency, which is the strength of  
2 the product, if you want to make it stronger, you have  
3 to dissolve more and you can only do that if you have  
4 the greater purity, that we didn't have.

5 Also, in terms of the dose size, the availability of  
6 plasma made it much easier to provide a greater dose  
7 size. I have already explained to you that we had to  
8 take a number of samples for quality control and if we  
9 had increased our dose size, the proportion that would  
10 have gone to quality control would have been even  
11 higher.

12 For example, to go back to the point I made where we  
13 had 150 bottles in a batch and we were taking 25 bottles  
14 for quality control, if we had increased the dose size  
15 and doubled the dose size to what some of the commercial  
16 companies were doing, then we would have only had  
17 75 bottles in the batch and we would have been taking  
18 25 bottles for quality control; that's one third of the  
19 batch.

20 So it's those kind of considerations made it really  
21 virtually impossible for us to compete, in terms of  
22 potency and purity, with the commercial companies, and  
23 that was really entirely down to the availability of  
24 plasma, that they had and that we didn't have.

25 Q. Are you describing the state of affairs around about the

1           early 1980s?

2    A.   I'm describing the state of affairs right through the  
3           1970s and 1980s.  If you go back to the availability of  
4           plasma and work it through, the commercial companies  
5           were providing 70 per cent of the world's needs.  They  
6           had huge quantities of plasma because of the system that  
7           they had, which was unique to the United States.  They  
8           had this reservoir, we had a dripping tap, basically,  
9           and we had to make the most we could of that.

10   Q.   Are these definitions in paragraph 51 of purity and  
11           potency the ones that we should be using as our working  
12           definitions?

13   A.   I said earlier that I would perhaps check with the  
14           article that Jim Smith wrote in the textbook at the time  
15           but, roughly speaking, yes.

16   Q.   Right.  Can we go back to the paper, please?  So in that  
17           second paragraph, which is page 42, it looks as though  
18           the Pharmacopeia were specifying a lower limit for the  
19           product in 1980 as well.  We saw Professor Ludlam's  
20           gradation of low, intermediate and high purity but to be  
21           described as the product at all, according to the  
22           Pharmacopeia, it would have to contain a concentration  
23           beyond a certain lower level.  Is that right?

24   A.   That's correct.

25   Q.   Yes.  Then you have explained in the next paragraph the

1 point you have just made, about all the elements that  
2 are in tension all the time and I think we can  
3 understand that, that additional processing to increase  
4 purity has a yield cost or a yield penalty and in the  
5 end you are obviously going to have to find a compromise  
6 between those. But in the result, commercial products  
7 often tended to be somewhat more concentrated and more  
8 potent.

9 Then you tell us that that changed. So that problem  
10 improved or the possibility of solving that problem or  
11 striking a better balance increased. Is that right?

12 A. Yes, there were some changes made in 1979 which  
13 increased the specific activity and increased the  
14 solubility of SNBTS product, quite a major step change,  
15 I think, in the convenience of the product.

16 Q. I think I should just ask you -- and perhaps I can do  
17 this before we stop for lunch, Dr Foster -- about some  
18 of the comments made by haemophilia clinicians so far.  
19 To do that, we need to go to the transcript. Could we  
20 go first to Professor Forbes on 28 April at page 27?  
21 Have you read some of the transcript?

22 A. I have read this one.

23 Q. Have you read it all?

24 A. Yes.

25 Q. Good. That may save some time.

1           Look at this page 27, from 28 April. It's  
2           four pages to a page. Yes, here we are. It's this  
3           section where I say.

4           "Question: Can I just backtrack a moment?"

5           Can you just have a look at that section and  
6           actually we go on through the next page and on to  
7           page 29. Let us all look at it in fact. (Pause)

8           Can we go on to 29, please? (Pause)

9           There is mention there, Dr Foster, of putting these  
10          points to people from the protein fractionation centre.  
11          Well, can I do that now?

12         A. Maybe we can take them one by one. If we start off with  
13          specific activity, I think I have gone over that one  
14          already, that, in order to achieve the purity, if you  
15          like, of the commercial products that would have been  
16          provided, we would have had to undertake further  
17          processing, which they had done, and that had a yield  
18          penalty. In order to do that, we would need more plasma  
19          and we didn't have that plasma.

20          The same applies to the potency because, in order to  
21          increase the strength of the material, you can only do  
22          that if it will dissolve and, to make it dissolve, you  
23          have to have the further purity. So those two things  
24          went together.

25          There is quite a lot of talk about solubility.

1 I think, generally speaking, this is the reconstitution  
2 of the product, how long it takes to do that. I would  
3 again agree that the commercial product would dissolve  
4 more quickly than our product, again for the same  
5 reason, that it was more purified; you had removed some  
6 of the less soluble material.

7 I'm a little bit less sure about some of the figures  
8 that are given here and I should say that in the  
9 Pharmacopeia, that we've talked about, the limit on  
10 reconstitution time is 20 minutes. We would not have  
11 released a batch for use if it had been greater than  
12 that.

13 As I mentioned a minute ago, we actually made  
14 improvements. For example, I have looked back at some  
15 of the data and in the 1970s the typical reconstitution  
16 time for our product was of the order of 12 to  
17 15 minutes and after 1979 it was down to 6 to 7 minutes.  
18 I haven't checked every batch, so I can't rule out the  
19 possibility that there might have been the odd batch  
20 that might have been longer than that, but that  
21 certainly wasn't typical.

22 Q. Can you just look at Professor Ludlam as well, please,  
23 from 3 May? It's page 42. Can we go towards the foot  
24 of the page, line 11, on to the following page?

25 A comment:

1           "Question: The initial clotting factor concentrates  
2           were relatively impure and contained large amounts of  
3           other plasma proteins. Are we talking about only NHS  
4           product here or about commercial product too?

5           "Answer: Commercial product as well."

6           Then could you just read on to --

7   A. Could I just comment on that, just to put that into some  
8           perspective?

9   Q. Yes.

10   A. You have talked earlier in these proceedings about  
11           albumin and the product that we manufactured called  
12           Stable Plasma Protein Solution, that had a purity of  
13           90 per cent. The immunoglobulin that we have talked  
14           about had a purity of about 99 per cent. When we look  
15           at Factor VIII concentrate, the purity is 0.01 per cent  
16           for our product, 0.02 per cent for the commercial  
17           product.

18   Q. That's back to the needle in the haystack?

19   A. It is not Factor VIII, it is Factor VIII concentrate and  
20           "concentrate" is the operative word, not "Factor VIII".

21   Q. Right. These early concentrates were very difficult to  
22           solubilise, if we go on to the next page. (Pause)

23           So he is making a point about dissolving the  
24           material, which I think you have just dealt with in  
25           fact, about your compliance with the specifications.

1 I suppose, comparatively speaking, people might have  
2 found the products from PFC slightly harder to dissolve  
3 than a commercial product. There is also the point you  
4 make about there may have been odd batches that were  
5 particularly difficult to dissolve.

6 A. I think there is no doubt that overall our product would  
7 take longer to dissolve than the commercial product  
8 because it was less pure. My comment about there might  
9 have been the odd batch that took longer was simply  
10 speculation, to try to accept the points that have been  
11 made here. Maybe there might have been a batch that was  
12 like that.

13 Another aspect to bear in mind is that this material  
14 is derived from cryoprecipitate. "Cryo" means "cold",  
15 "precipitate", it's insoluble. It actually doesn't  
16 dissolve if it is cold. These products are stored in  
17 the fridge. So, in order to dissolve them, you have to  
18 allow them to warm up and if somebody tried to dissolve  
19 it when it's cold, then it won't dissolve. That maybe  
20 is something that has happened from time to time, if  
21 people are not doing this properly.

22 Q. I wondered in a sort of low-tech way actually, when  
23 Professor Ludlam was talking, whether it would be  
24 permissible to heat the water.

25 A. It would be, yes, and I think you find reference to that

1 in the preliminary report, where Mr McIntosh, who was  
2 our general manager much later on, said:

3 "This problem can be solved for the price of a water  
4 bath."

5 Q. Right. I think, sir, that would be a good point to  
6 stop.

7 THE CHAIRMAN: Very good.

8 MS DUNLOP: If that's all right.

9 (1.11 pm)

10 (The short adjournment)

11 (2.00 pm)

12 THE CHAIRMAN: Yes, Ms Dunlop?

13 MS DUNLOP: Thank you, sir. I think, Dr Foster, we had been  
14 talking just before lunch about purity and potency and  
15 then you were looking at what has been said by two of  
16 the haemophilia clinicians about PFC products.

17 Can we return to your paper, please --

18 A. Before we move on, could I just make one further comment  
19 on some of the points that have been made previously.

20 One of the issues that has been raised is that our  
21 product didn't always work, and I think that

22 Dr McClelland began to talk about that last week.

23 I have really tried hard to think why anyone would make

24 that comment because our product was licensed, it had

25 been evaluated in patients before it received a product



1 licence. It was tested by an approved method by NIBSC.  
2 So really I can't understand why it wouldn't have  
3 worked. The only explanation I can come up with is that  
4 we did provide a product that might have a variable  
5 quantity from batch to batch in the vial.

6 We aimed to have a vial that would contain in the  
7 range of 200 units to 250 units, and that variation was  
8 simply a reflection of the type of plasma that we  
9 obtained. We have seen earlier how our plasma might be  
10 frozen within six hours or even 18 hours, and because  
11 Factor VIII is very sensitive and loses its activity  
12 over that timescale to some extent, then that meant the  
13 batch of Factor VIII from 18-hour plasma might have less  
14 in it than a batch of Factor VIII from six-hour plasma.

15 Compared to the commercial companies, that wouldn't  
16 be the case, because where they are collecting plasma in  
17 a fixed location, by plasmapheresis, they can freeze  
18 that material almost immediately after it has been  
19 collected. So their product would be more uniform  
20 because their plasma was more uniform. Our products  
21 might be less uniform because our plasma was less  
22 uniform, and that led us into a position where we might  
23 have this variation from batch to batch. And therefore,  
24 to accommodate that situation, we would print on every  
25 vial the amount of Factor VIII in the vial, but it would

1           be incumbent on the doctor or the patient to read the  
2           label to work out how much to treat themselves with or  
3           how much to administer. If they didn't do that, if they  
4           just took a vial and assumed what was in it, it's  
5           possible that they might have got that wrong. That's  
6           the only explanation I can come up with for that comment  
7           that was made.

8    Q. I can remember Dr Forbes saying something about a lack  
9           of correspondence between what was on the bottle and  
10           what was in the bottle, and Dr Ludlam referring to the  
11           product not working in one patient, but you are alluding  
12           to a comment by Dr McClelland, are you?

13   A. No, Dr McClelland began to answer that question.

14   Q. I see.

15   A. And he said you would refer it to me and he gave half an  
16           answer, if you go back and check the transcript.

17   Q. I see.

18   A. So I'm trying to imagine what it was that led to these  
19           comments from Dr McDonald and Dr Ludlam, and that is the  
20           only explanation that I can come up with, that we did  
21           have a wider variation from batch to batch in terms of  
22           what was in the vial.

23   Q. I'm just clarifying so that I know when I go back and  
24           look at the transcript, when I come to that part I need  
25           to read this section of your evidence so that

1 I understand what the link is. So, thank you.

2 I think we need to go back to table 9, which is  
3 shown on [\[PEN0131125\]](#) at 1166. This is page 42.  
4 Different types of blood product. You can go on to the  
5 following page. This is really again picking up some of  
6 the points you made when we talked about purity and  
7 potency. Indeed, we can see what was ultimately  
8 achieved with Liberate, for example, Liberate and  
9 Replenate.

10 A. Yes.

11 Q. Really very much higher than, for example,  
12 Cohn Fraction I. And no doubt these sorts of very high  
13 purity products require much smaller infusions, do they?

14 A. You are able to put more Factor VIII into a smaller  
15 volume, yes.

16 Q. Yes. We have had some reference to the need for small  
17 infusions when treating small children, for example. Is  
18 that a factor?

19 A. Yes, I think these very high purity products would have  
20 that advantage in children because of that, yes.

21 Q. Then in section 6.2, you chronicle for us the  
22 introduction of different products, and we see mention  
23 of Dr Johnson again at the bottom of the page.

24 If we look on to the next page, there is a reference  
25 to requirements being uncertain and we understand about

1           that. I suppose in doing the necessary predictions when  
2           planning manufacture, we have already discussed the  
3           constantly spiraling demand, but there must also have  
4           been difficulty -- and I think you are alluding to this  
5           here -- in knowing how much cryoprecipitate was going to  
6           be used and how much plasma would then be sent for the  
7           making of the concentrates. So that would be an added  
8           difficulty when you were trying to predict what was  
9           going to happen in future. Is that fair? Even the  
10          breakdown was uncertain?

11        A. I think to some extent it was uncertain but there was  
12          certainly obviously clear indications from haemophilia  
13          directors what their preference was. But I think there  
14          were times when Professor Cash was saying to them,  
15          "Would you like more cryoprecipitate", and the message  
16          coming back was, "No, we don't".

17        Q. Right. Then you mention this freeze-dried cryo on this  
18          page and we looked at that before lunch as well.

19        THE CHAIRMAN: Ms Dunlop, do you deal with Superate at any  
20          stage?

21        MS DUNLOP: I hadn't planned to.

22        THE CHAIRMAN: Perhaps just something I ought to raise with  
23          you. I found it very difficult to pin down what  
24          happened to the Superate project. Can you sum it up in  
25          just a brief sentence?

1 A. I think there are two things here. One is Supernine and  
2 there is an S8 that was a development --

3 THE CHAIRMAN: Sorry, I have confused the two. It is the  
4 Factor IX product.

5 A. The Supernine was a Factor IX concentrate that was more  
6 highly purified, more potent, hence the name "Super",  
7 and it had a step that was deliberately introduced for  
8 removing viral contaminants and that got through to the  
9 point of some clinical trials and then, as far as  
10 I understand it, Mr Watt was talking to the licensing  
11 division, medicines division, and they wanted us to have  
12 only one Factor IX concentrate and we had a choice. We  
13 could either go with Supernine or we could keep the  
14 traditional product, which was called DEFIX. And at  
15 that time the haemophilia directors were more confident  
16 with DEFIX because they had a lot of experience with  
17 that, they knew it worked. So the choice was to stay  
18 with DEFIX. Supernine was discontinued. And this was  
19 at a time when heat treatment was being developed and it  
20 was thought that was going to be better anyway. It  
21 superseded it.

22 THE CHAIRMAN: That's fine. I had seen the relationship  
23 between DEFIX and Supernine in some correspondence but  
24 if that is the whole story, I'm quite content to park it  
25 at that. Anyone else who wishes to raise this can of

1 course do so, but I would be happy to leave it there.

2 MS DUNLOP: Dr Foster, in table 10 you have listed

3 coagulation factor products. Earlier Factor IX products

4 didn't give you just Factor IX but you had an omnibus of

5 Factor II, VII, IX and X. I'm chancing my arm here but

6 are these other factors which co-purify in some way with

7 Factor IX?

8 A. That's absolutely correct and another term for this is

9 the prothrombin complex. That would be the term that

10 medical doctors might use because these proteins all

11 exist in a very similar part in the human body, and they

12 are all synthesised in the liver. There is a deficiency

13 of these proteins in the liver that can cause the

14 bleeding difficulties and a number of disorders. So

15 this product would be used not only to treat haemophilia

16 but also it might have been used for people who had

17 disorders of the liver as well.

18 Q. Right. What does "PPSB" actually stand for?

19 A. You have got me there. It is a French term and I have

20 to think back on the French words to get what they

21 actually were.

22 Q. I don't think it matters.

23 A. I think it was to do with someone called Stuart factor

24 and prothrombin complex. It got changed around in

25 French.

1 Q. That's fine. We will just call it "PPSB".

2 A. In the preliminary report it is referred to as the  
3 method of Soulier.

4 Q. I suppose the thinking must be that for people with  
5 Haemophilia B, there was no particular downside in  
6 giving them something that is Factors II, VII and X in  
7 it as well?

8 A. It wasn't ideal but at that time there was no means for  
9 purifying Factor IX on its own. So this was the best  
10 that could be done, and as these types of products were  
11 used and began to go into wider use, there were side  
12 effects that emerged -- I think you have heard about  
13 that from Professor Ludlam -- to do with thrombogenic  
14 reactions. They were never fully explained I don't  
15 think, but they were partly to do with the degree of  
16 purification and maybe some of these other factors that  
17 are in there that weren't really necessary for the  
18 haemophilia patients, and so the purification of this  
19 product became important subsequently to deal with that  
20 issue.

21 Q. We have certainly seen references, and I think it is  
22 true around the time when heat-treated Factor IX comes  
23 in in 1985, references to the need for thrombogenesis  
24 studies in dogs?

25 A. Yes. This was seen as being quite a serious

1 complication, a potential complication of Factor IX  
2 treatment, that you would have these thrombogenic  
3 reactions. I think in the United States people died  
4 from these reactions. So it wasn't a trivial issue and  
5 in Edinburgh Professor Cash had pioneered quite a lot of  
6 work in this area in animal studies and because the  
7 mechanisms weren't known biochemically, the only way you  
8 could be certain that you hadn't actually caused  
9 a product to change and be thrombogenic was to do these  
10 studies in animals. So we did have a very substantial  
11 study that was done jointly with BPL, led by  
12 Professor Cash.

13 Q. Table 10 runs on to the following page and we can see  
14 a list up to 1996. Then in the next section, 6.3, you  
15 deal with commercial products, and moving on to the  
16 following page, you refer to approval by the Committee  
17 On the Safety of Medicines since 1973 and  
18 recommendations from haemophilia directors. We have  
19 seen a number of references ourselves. UKHCDO meetings,  
20 where no one voted for cryo if there was a choice  
21 between cryoprecipitate and Factor VIII concentrate.  
22 You have listed the principal commercial Factor VIII  
23 concentrates approved for use in the United Kingdom and  
24 I referred to this earlier on this morning. It's  
25 a table which gives different pieces of information



1 about these pharmaceutical products.

2 On to the next page, quite a complicated exercise  
3 keeping track of the companies in their different  
4 incarnations and different ownerships, Dr Foster.

5 A. Extremely complicated, yes.

6 Q. I think I noticed one of the things when I was looking  
7 at this table, that I had referred to Armour. I may  
8 have said in evidence about Armour becoming French.  
9 I think that's in the Douglas Starr book. But indeed  
10 you have taken that story on for us in footnote (f), and  
11 Armour is now part of Behring?

12 A. Rhone Poulenc was French. So you were correct in the  
13 reference to France but it is now CSL Behring.

14 Q. You have explained too, something which I hadn't picked  
15 up, the references to Speywood. That Speywood sold  
16 a Cutter product, presumably repackaged, remarketed as  
17 Humanate. That is note (k). And then you go on to talk  
18 about market shares in table 12. Quite interesting.  
19 Not least because it is not the same as another table  
20 that I have seen, which we can just look at. I don't  
21 think this matters in the slightest but can we look at  
22 [\[DHF0014517\]](#), please? Just slightly different figures,  
23 Dr Foster, and I suppose illustrating how difficult it  
24 is to get the definitive answer?

25 A. Yes, I would like to say, the difference might be

1           because this table here is given in units of  
2           Factor VIII, and I think much of the other table might  
3           be in sales, and depending on the pricing of the  
4           products between different companies, the sales might be  
5           different too.

6   Q.   Yes.  It was just that, looking at the Department of  
7       Health table, the DHSS table, for 1980, they are showing  
8       Armour as somewhere approaching 50 per cent of the UK  
9       market, which isn't quite what you have.  On your table  
10      Armour is obviously a very big supplier in 1980.  I just  
11      wondered why Armour -- was their product particularly  
12      good?

13   PROFESSOR JAMES:  It's the same.  This is the 1980 figure  
14      for Armour of 34 per cent is 34 per cent of the total UK  
15      market including the UK production.

16   MS DUNLOP:  Right.  Okay.  Whereas the Department of Health  
17      one is excluding UK production.

18   PROFESSOR JAMES:  Exactly.

19   MS DUNLOP:  Yes, right.

20   PROFESSOR JAMES:  So here on table 12 of Dr Foster's, it  
21      says:

22                "All 71 per cent share of UK supply."

23                So they have half of 71 per cent, which is 34 --

24   MS DUNLOP:  I see that, thank you.

25                I just wondered, Dr Foster, do you have any

1 recollection of why Armour enjoyed such a large slice of  
2 the market?

3 A. I really can't answer that. I know they had a sales  
4 office in the UK, which I think may have explained it.  
5 They had a strong presence here. But that's really all  
6 I can suggest.

7 Q. Just going back to your paper. You mentioned the WHO  
8 policy and then Dr Galbraith's initiative in 1983 and  
9 indeed, steps taken by ASTMS, and I want come on to that  
10 because you have covered that in your statement as well.  
11 Then on to the following page you mention the  
12 correlation between HIV infection of people with  
13 haemophilia in the UK and the use of commercial  
14 concentrates. You refer to work by Melbye. Denmark and  
15 Glasgow. I don't remember where the Moffat work was  
16 based. I don't think that's work at which we have  
17 looked but conclusion to the same effect. Something in  
18 the Lancet in 1985 in which Dr Mortimer and  
19 Professor Bloom also took part. Then you go on to talk  
20 about the detection of antibodies to HIV.

21 The next paragraph in which you deal with antibody  
22 to Hepatitis C, I think, Dr Foster, we need to look at  
23 all of this in more detail when we come to look more  
24 specifically at Hepatitis C, but at first sight this  
25 seems slightly puzzling, what's in the paragraph

1 beginning:

2 "This much greater prevalence of Hepatitis C  
3 infection amongst USA paid plasma donors was reflected  
4 in the different levels of Hepatitis C antibody detected  
5 in plasma pools from which coagulation factor  
6 concentrates used in the UK were prepared. 89 per cent  
7 of plasma pools from commercial manufacturers were  
8 positive for antibody to Hepatitis C compared with none  
9 for UK donor plasma."

10 That's research that was done towards the end of the  
11 1980s, presumably?

12 A. The author here is Phil Minor, who worked at NIBSC and  
13 because NIBSC were monitoring products, they were also  
14 looking at the plasma pools. So he had access to plasma  
15 pools from all of the manufacturers and he published  
16 this information in 1990, using what must have been the  
17 first generation antibody test, and using that test, he  
18 wasn't able to detect antibodies in the UK plasma donor,  
19 presumably because it was too diluted, not because it  
20 was absent. Whereas it was present in the pools from  
21 commercial plasma.

22 Q. Right.

23 THE CHAIRMAN: Is this raising the terrible topic of  
24 genotypes again?

25 MS DUNLOP: I suppose it might. Given that it's a slightly

1 surprising proposition at first blush, I think it's  
2 probably better that we defer it and look at it when we  
3 come to look at hepatitis in more detail. It may well  
4 be to do with the different genotypes, at least in part.

5 THE CHAIRMAN: We have heard some evidence of the  
6 ineffectiveness of the first generation Abbott test to  
7 pick up infection in the United Kingdom because it was  
8 largely based on experimental work with American blood,  
9 where the balance within the genotype spread is rather  
10 different.

11 A. I mean, this is not my area of expertise so I'll defer  
12 to other people on this one.

13 MS DUNLOP: Then you talk about commercial products free  
14 from the risk of hepatitis transmission. I think all of  
15 which we will defer.

16 Then finally in this section on the next page you  
17 tell us about SNBTS having imported some plasma after  
18 1998, and then we move on to a section on yield,  
19 section 7, and I think we understand from earlier  
20 discussion about the importance of yield. The  
21 importance of yield in absolute terms and also as an  
22 assumption. You have given us another table, table 13,  
23 to show how the yield changed, indeed improved, and you  
24 go into this in more detail in section 7.2. You say:

25 "Normal plasma contains one international unit of

1 Factor VIII activity per millilitre by definition."

2 So that is how an international unit was first  
3 identified, is it? It's the activity of Factor VIII in  
4 1 millilitre of plasma?

5 A. Of a normal person.

6 Q. Of a normal person. But that even begins to decline  
7 when anti-coagulant is put into the donation?

8 A. That's simply the dilution because the definition  
9 applies to circulating Factor VIII in the human body and  
10 of course, when you take a blood donation, you have to  
11 add an anticoagulant to prevent it clotting, and that  
12 adds a dilution. So once you get into the blood  
13 donation or the plasma, there is that dilution to take  
14 into account.

15 Q. So it's not a chemical effect, it's just a physical  
16 effect?

17 A. It actually turns out to be a chemical effect but at  
18 this point it's a physical effect.

19 Q. Then you go on to talk about other chemicals which are  
20 used in the early stages of the process, which is,  
21 I think, quite technical for us, Dr Foster. Collecting  
22 plasma in a reduced concentration of sodium citrate, but  
23 not pursued because of potential for thrombogenicity.  
24 Optimisation of process conditions. We can just perhaps  
25 note the thinking there. Then, 7.4, increased yield and

1 quality being improved by a continuous thawing. I think  
2 that's something that we saw earlier today as well,  
3 isn't it, about improving the yield of cryoprecipitate?

4 A. Yes, there are similarities. What was called a thaw  
5 siphon method in the blood bank has some similarities  
6 with what we were doing at PFC, which I have called  
7 continuous thawing, which is to have a much better  
8 control of this whole process to try and improve the  
9 yield because this is a point of major loss of yield.

10 Q. Perhaps we can move on to the next page, all of this  
11 dealing with really the thawing step, and then, 7.5, the  
12 addition of calcium. Again, rather technical, although  
13 you have set it out very fully for us. Thank you.

14 The addition of calcium, which is discussed if we go  
15 on to the next page. The addition of calcium, which  
16 reduced the degree of yield loss and the addition of  
17 sodium chloride, it looked as though these were both  
18 steps that that were really steps for which you at PFC  
19 deserve the credit. These were ideas at PFC, were they?

20 A. Well, you learn from other people as well but  
21 predominantly we took this forward, yes.

22 Q. You say that calcium addition has since become widely  
23 used and you also say that about the addition of sodium  
24 chloride.

25 Then section 8, you have supply of SNBTS products

1 for Haemophilia A. Can we move on to the next page?  
2 Two products, cryoprecipitate and Factor VIII  
3 concentrate. Both products being supplied to the NHS in  
4 Scotland free of charge.

5 Table 14, you have shown the amounts of  
6 cryoprecipitate produced as well as Factor VIII  
7 concentrate issued. We can see from 1975 to 1976  
8 onwards, again a steady increase, in the column on the  
9 furthest right. A bit of fluctuation in the internal  
10 division perhaps but a steady increase in the amount of  
11 material issued.

12 On to the next page. The cryoprecipitate ceasing  
13 altogether in fact in the year 1990 to 1991.

14 A. Cryoprecipitate is used for other indications other than  
15 Haemophilia A. So, for example, that would be used to  
16 treat patients who need fibrinogen. So in earlier  
17 tables I had listed cryoprecipitate production, we  
18 couldn't say that all went to treat haemophilia.

19 I think by 1990 period, there were recommendations from  
20 the haemophilia doctors to cease using cryoprecipitate  
21 and I think it completely went out of use at that point.  
22 So I have not included it in the table after that.

23 Q. As we move on, you talk about -- going down the page  
24 a little bit, please -- the monitoring of Factor VIII  
25 use being undertaken by UKHCDO and you can use these



1 data to work out the amount of Factor VIII per head of  
2 population and compare this with the amounts supplied by  
3 SNBTS. You have done that in table 15 for  
4 cryoprecipitate and Factor VIII concentrate combined and  
5 for Factor VIII concentrate alone. Perhaps we can study  
6 table 15. If we take, for example, the year 1979 to  
7 1980, this is a year in which, for the UK, the average  
8 use of Factor VIII in international units per head of  
9 population is 0.93 including cryoprecipitate; 0.77  
10 excluding cryoprecipitate.

11 Looking to see from the other side of your table the  
12 extent to which the clinical use was matched by supply  
13 from SNBTS, if you take cryoprecipitate into account,  
14 you were producing -- you, as in SNBTS -- 107 per cent  
15 of what was being used, but if you exclude  
16 cryoprecipitate and look therefore only at concentrate,  
17 you were only producing 54 per cent of what was being  
18 used, if what was being used is measured as  
19 international units per head of population.

20 Is that right? So it makes a big difference whether  
21 you take cryoprecipitate into account or not?

22 A. Yes, and it goes back to the earlier figures where you  
23 saw that Scotland carried on using cryoprecipitate, or  
24 a greater proportion of cryoprecipitate, longer than  
25 England, and England took up commercial products to

1 a much greater extent.

2 Q. Yes. Then if we look at the following year, there is  
3 quite a change for the following year. Again, if you  
4 were to assume that the usage in the UK mirrored the  
5 usage in Scotland, then for 1980 to 1981, the usage  
6 excluding cryoprecipitate would be 0.91 international  
7 units per head of population, and of that use, SNBTS was  
8 able to provide 76 per cent and then a further increase  
9 1981/1982. So we are back to the runner and the race.  
10 Certainly, in this period, maybe 1978 to 1979, up to  
11 1981/1982, you look to be gaining on the runner although  
12 not yet pulling alongside. Excluding cryo.

13 A. Yes, I mean, this is all kind of looking back.

14 Q. Yes.

15 A. And at the time we didn't have these figures, so we were  
16 just doing as much as we possibly could. But looking  
17 back, we can now see, now the darkness has been lifted,  
18 we can see where we were.

19 Q. Yes. The really significant change obviously comes by  
20 the time you get to 1983 to 1984, where even excluding  
21 cryoprecipitate, SNBTS is producing 116 per cent of the  
22 average use, again average use being calculated on  
23 a UK-wide basis. That's a first. That has not been  
24 achieved at any earlier point in the table.

25 Although -- and you make this point in your paper,

1 Dr Foster -- the position is different if you take  
2 cryoprecipitate into account as well?

3 A. And the position is different if you look at Scotland on  
4 its own because this makes the assumption that clinical  
5 practice in Scotland is the same as the rest of the UK.

6 Q. Yes, and we go on to do that. So if we move on through  
7 the paper and look at the following page, table 16,  
8 where you have these figures for use, you explain has  
9 been appendix 1 of the preliminary report. I didn't  
10 completely understand this reference in the paragraph  
11 above the table, but you say:

12 "Data have been obtained from individual records of  
13 every batch of Factor VIII concentrate."

14 What did you do with that information? Why did you  
15 need that?

16 A. Column 1. In this table we are looking at calendar  
17 years. That's from January to December. All the other  
18 data from SNBTS is expressed in the financial year.  
19 Whereas the clinical data from the haemophilia centre  
20 directors' organisation is a calendar year, not  
21 a financial year. So to make a more precise comparison,  
22 we needed to go back and get data for the calendar year  
23 for PFC production, and the only way to do that was to  
24 go back to the raw data. So my colleague did look at  
25 the data files to allow me to assemble this table and

1           that's in column 1. That shows how much was produced  
2           each of these calendar years from PFC.

3    Q. And the reason you had to go to every batch is because  
4           there may have been differences in the number of units  
5           from batch to batch.

6    A. We definitely knew there were, yes. The only way you  
7           could get the information was to go back to the raw  
8           data, because the data that had been collected from  
9           management records had been done only on a management  
10           basis but it was on a financial year. So the only place  
11           where you could get the data was really to go back and  
12           look at each batch and add it up for each calendar year  
13           from the original orders.

14   Q. Was this quite a major exercise?

15   A. It took a few days.

16   Q. How many batches, roughly, would we be talking about?

17   A. 70 or 80 batches a year.

18   Q. Right. Okay. And then we have again, quite an  
19           illuminating exercise in the table. If we look at the  
20           two middle columns, so column 2 and column 3, this is  
21           the amount of SNBTS Factor VIII used clinically, and  
22           then the amount of commercial Factor VIII used, and  
23           that's totalled in the fourth column, and then we  
24           compare that with the amount that was produced.

25           So for 1979, the amount that was produced is greater

1 than the amount that was used. For 1980 the amount that  
2 was produced is less than the amount that was used, and  
3 the other interesting thing to note is that from 1979 to  
4 1980 there has been a doubling in the total amount used,  
5 from 2.48 to 4.83, more or less.

6 Then we can follow on for ourselves how the figures  
7 go: 1981, more produced than used; 1982, more produced  
8 than used, and so on.

9 I think it's necessary to come back to this table  
10 but it's obviously an important table for our purposes.  
11 You say, reading the text from the bottom of the page,  
12 that:

13 "In order to maintain supplies of essential  
14 treatment at a time when demand was uncertain, the SNBTS  
15 supply chain comprised stocks of Factor VIII concentrate  
16 stored at the regional transfusion centres and a reserve  
17 stock held at the PFC, in addition to stocks held at the  
18 haemophilia centres and at the homes of individual  
19 patients."

20 There is quite a lot in that, Dr Foster. I suppose  
21 this is really logistics. If you think of the patient,  
22 the patient needs a stock in his fridge, the hospital  
23 from which he gets his supplies needs to have a stock,  
24 the regional transfusion centre from which the hospital  
25 gets its supplies needs to have a stock and PFC from

1           which the regional transfusion centre gets its stock  
2           also needs to have a stock. How did you do all that  
3           stock control?

4    A. I'm not the person to ask that question because really  
5           I wasn't involved with that at all. You might try  
6           asking Dr Perry or Dr Cuthbertson.

7    Q. I think we will ask Dr Perry, since he is coming, but  
8           even that very crude sketch, it does sounds as though  
9           there might have been a lot of forward planning  
10           involved.

11   A. I think there was a considerable lot of planning  
12           involved. Today we would call this the supply chain.

13   Q. Right. Then you say you have included stocks held at  
14           the regional transfusion centres in the amounts of  
15           concentrates supplied by SNBTS in table 15. But you  
16           haven't included the stock of Factor VIII concentrate in  
17           storage at PFC. Then you have listed that for us.

18   A. I should really make it absolutely clear that these  
19           figures are the stock taken at the end of each year  
20           shown here. These are not cumulative figures at all.  
21           It is just the product in stock at that point in time.

22   Q. It's just a snapshot?

23   A. Exactly.

24   Q. And for all we know demand may fluctuate on a seasonal  
25           basis, I don't know.

1 A. I think one of the problems with haemophilia is demand  
2 fluctuates unpredictably. You can get patients who  
3 might have a severe bleed, who need emergency treatment.  
4 So you can have fluctuations, and I think that has been  
5 pointed out already in these hearings, that they would  
6 have to be accommodated.

7 Q. Yes. Just to take a for instance, if we look at what  
8 must be the end of March 1981, so that's in the year  
9 column, 1980 to 1981, because these are financial years,  
10 as I understand it, so the end of March 1981 at PFC  
11 there was 1.56 million international units of  
12 concentrate in stock, which is about a third of the  
13 usage for the last full calendar year. It should be  
14 1980. I'm taking that by going back to table 16 and  
15 seeing that the total amount used in 1980 was  
16 4.83 million international units.

17 So it would really be up to somebody who was  
18 experienced in stock control and so on to tell us  
19 whether that's a reasonable cushion to hold or not.  
20 I think we go on to read that the sorts of stocks that  
21 were built up in different places, at least in some  
22 areas, increased hugely. But just to get an idea of  
23 what that level of stock would correspond to, it's about  
24 four months' use. That's exactly what you say in the  
25 table.

1 THE CHAIRMAN: I imagine lots of different factors would  
2 enter into the determination of the appropriate level of  
3 stock, such as whether their phased refurbishment of PFC  
4 was expected, and you would have to cover a period of  
5 low production and so on.

6 A. That's quite right. I mean, the stock level is to cover  
7 emergencies and contingencies, and the contingencies  
8 could include stoppage of production for whatever reason  
9 in PFC and breakdown of equipment as well as medical  
10 emergencies.

11 MS DUNLOP: The next table is interesting too. That's table  
12 18. Can we go on and look at that, please? This is  
13 really a similar exercise to that at which we looked a  
14 short time ago. You have tabulated the total SNBTS  
15 Factor VIII available in terms of million units per head  
16 of population, and to what extent that was matched or  
17 that matched the clinical use. Your conclusion, which  
18 is reproduced under table 18, is that:

19 "At any point in time, SNBTS had available  
20 sufficient Factor VIII to meet average UK clinical  
21 practice if cryoprecipitate was considered to be  
22 suitable to supplement Factor VIII. If it is excluded,  
23 [so if it is not considered to be suitable] then, with  
24 the exception of the two-year period, 1978/1979 to  
25 1979/1980, the availability of Factor VIII concentrate



1 from SNBTS was sufficient to meet average UK clinical  
2 use throughout that period."

3 I think the chairman has just made this point: of  
4 course, that's not the end of the story because you have  
5 to have enough material produced at the right time and  
6 in the right place when it's needed. To say that on the  
7 ground a need was met, and that would be presumably  
8 impossible to assess in retrospect. I mean, do you  
9 think it's possible, even given these figures that you  
10 have worked out now, Dr Foster, that a clinician could  
11 have felt around about 1979/1980 that there wasn't  
12 a reliable enough supply coming through?

13 A. I'm really not sure how to answer that question.  
14 I don't know where the clinicians were with our stock  
15 situation, I don't know. They may have been  
16 well-informed or they may not. I just can't answer  
17 that.

18 Q. It is very difficult, Dr Foster, because it is such  
19 a long time ago and people, in some instances, are  
20 telling us things second or third hand, but Dr Pettigrew  
21 said, for example, that Dr Willoughby at the Hospital  
22 for Sick Children in Glasgow had felt he couldn't get  
23 a guarantee of reliable supply or a reliable guarantee  
24 of supply.

25 A. I think if you go back into the 1970s, when PFC was

1 really still getting going and usually doctors were  
2 moving forward with home therapy, there is clearly  
3 correspondence where SNBTS is really saying, "Look, we  
4 can't provide more at the moment, and the choice is for  
5 you", and they decide to buy commercial product because  
6 they want to do home therapy. So there is a period when  
7 clearly there is a discontinuity between the aspirations  
8 of the clinicians and what we can provide.

9 Q. I suppose particularly, if we look from the furthest  
10 right column, 1978/1979, 1979/1980, if Dr Willoughby  
11 reached that view around about that time, then it may be  
12 that there is some support for that in these figures,  
13 that the clinical use is ahead of the available  
14 Factor VIII at that time from SNBTS. That then pulls  
15 back again in 1980/1981, 1981/1982. So for somebody  
16 intent on using concentrate, as you say, it's very  
17 difficult to answer but one couldn't rule that out  
18 around about that time, that somebody intent on using  
19 concentrate might feel that there were difficulties of  
20 supply around about that time.

21 A. I would agree with that. I mean, we were quite clear  
22 that we were not able to provide enough concentrate. We  
23 couldn't meet the aspirations and we were always chasing  
24 this moving target.

25 Q. Yes. Can we look on to the next section, which is about

1 commercial products in Scotland. You have done your  
2 best to list those as well.

3 We can see it is really over quite a long period.  
4 One can do all sorts of exercises with these figures,  
5 Dr Foster, and trying to work out for the period of  
6 years, 1979 to 1982 inclusive, which is obviously  
7 a period that's of interest to us from the point of view  
8 of looking at what happened at Yorkhill, the first  
9 problem, if you are trying to do that from table 19, is  
10 that obviously these are financial years, not calendar  
11 years, but trying to approximate, therefore, for 1979  
12 and 1982, by assuming that the usage is equal throughout  
13 the 12 months, which no doubt it's not, and get  
14 commercial usage for that four-year period and then go  
15 back and look at table 16, there did appear to be  
16 a slight discrepancy in that your figure from the  
17 information you held, or SNBTS held, about the use of  
18 commercial product seemed to be slightly higher than our  
19 figures in an appendix 1 of the preliminary report. Is  
20 that right?

21 A. Yes, and one possible explanation is that your figure is  
22 usage and our figure is purchase.

23 Q. Right. Okay. Another explanation, and I think Dr Hay  
24 said this, is that the data may be incomplete?

25 A. Yes, that may be another explanation. One other point

1 to bear in mind is that Factor VIII has a shelf life of  
2 two years, so if you purchase it in one year, it might  
3 not get used for the next year or even the year after  
4 that. So trying to match these figures equally across  
5 usage and purchase, they may not end up in the same  
6 columns.

7 Q. Yes. Just for the record -- I'm not sure if I made this  
8 clear -- some of this is rather difficult material with  
9 which to work but your figures are slightly higher than  
10 UKHCDO, and you say one explanation may be that their  
11 figures are use and your figures are purchase?

12 A. I'm sure their figures are use and our figures are  
13 purchase.

14 Q. Yes. Then moving on to the next page, you have given  
15 a breakdown in table 20 on a regional basis of the  
16 purchase of commercial Factor VIII concentrate. Were  
17 these figures obtained at the time, Dr Foster?

18 A. They were obtained by Professor Cash and I would need to  
19 go back through the minutes of the various meetings just  
20 to see when he obtained them, and perhaps you could  
21 maybe put that question to him but they were close to  
22 the time, yes.

23 Q. I mean, I suppose opening up before us is another area  
24 in which there may be discrepancy, and that is that what  
25 was being said at meetings by way of information about

1 amounts purchased might not have been the same. You  
2 hear all sorts of reasons why people might have the  
3 wrong figure in their head; you might get a different  
4 figure from a regional transfusion director from  
5 a figure you would get from a hospital pharmacist.

6 A. I think this wasn't at all straightforward.

7 Q. No.

8 A. I think you have probably recognised that Professor Cash  
9 brought in Dr Stewart later on to try and get a better  
10 grip on this and made some progress. So it was  
11 a difficult area to try and get a handle on.

12 Q. Rather than worrying too much perhaps about mathematical  
13 accuracy and trying to get all the figures to balance,  
14 which is not easy, we can certainly understand the  
15 general picture, if we look at table 20, which is that  
16 there is commercial Factor VIII concentrate being bought  
17 in Glasgow in 1978 to 1979 and 1979 to 1980, and then at  
18 more or less the same level, 1980 to 1981, slightly  
19 dropping, 1981/1982.

20 Comfortingly that does seem to reflect the  
21 information we are given about use and which we  
22 reproduced in appendix 1 to the preliminary report. The  
23 figures no doubt are not the same but the pattern is  
24 similar. Yes. Then for Edinburgh, no commercial  
25 purchases 1978/1979 or 1979/1980, and that again fits

1 with what we have heard about Dr Davies and his  
2 policies. Then small amounts of commercial material  
3 from 1980/1981 onwards.

4 You no doubt know this: Dr Ludlam has given us  
5 a table detailing patient by patient those who received  
6 commercial concentrate and an explanation of why.

7 Then on to the next page, you have given us some  
8 percentages, that reference at the end of the first  
9 paragraph to imported Factor VIII concentrate being used  
10 at the Royal Hospital for Sick Children in Glasgow comes  
11 from the minutes of the meeting on 29 November 1984,  
12 which I think was attended by Dr Brenda Gibson, and she  
13 reported. In fact, what she said, I think, Dr Foster,  
14 was that imported concentrate had been used until  
15 recently. You have interpreted that as perhaps meaning  
16 1984.

17 You go on to talk about the incidence of overt non-A  
18 non-B hepatitis and you say that:

19 "For the period 1980 to 1982, SNBTS Factor VIII  
20 concentrate was associated with the lowest degree of  
21 overt transmission of NANBH in the UK."

22 I thought we should just look at that. That's  
23 [\[SNF0010948\]](#). Can we go on to page 8 of this document,  
24 please. Is this your source, Dr Foster?

25 A. That's correct.

1 Q. Can you just explain to us where you take the  
2 information from, please?

3 A. Well, the table shows that for each of a number of three  
4 years here, the number of patients treated with various  
5 products, various concentrates, both commercial and  
6 material from ourselves and from NHS in England, and if  
7 we look at the number of cases of non-A non-B hepatitis  
8 recorded here, which is kind of in the centre of the  
9 table, then in those three years there is only one case  
10 for the Edinburgh concentrate, and the other products,  
11 as far as I can see, with the exception of Speywood's  
12 humanate, which is only used in a small number of  
13 patients, have more cases of non-A non-B hepatitis  
14 associated with them.

15 Really, all I'm saying is that is all the  
16 information that was available at the time and this is  
17 the information that people would have been trying to  
18 make an informed decision on.

19 Q. Of course, as you say yourself in your paper, this is  
20 overt non-A non-B hepatitis?

21 A. That's correct.

22 Q. So this is people who actually got ill?

23 A. Yes, people turning yellow or whatever they do.

24 Q. If we go back to the paper, please, back to page 63, to  
25 the question of stock in fact, you say that when

1 Dr Perry looked into questions of stock, he found that  
2 in November 1982 the stock had stood at approximately  
3 5 million international units and had risen to  
4 approximately 7 million international units  
5 by November 1983.

6 I think, just so that we can actually see that, we  
7 should look at [\[SNB0073984\]](#). As far as he says, there  
8 has been a steady increase in stock over the past year,  
9 in a year which was not particularly outstandingly  
10 productive. So by this point, certainly as assessed by  
11 Dr Perry, there seems to be an excess annual output and  
12 understandably his concern is that you don't want to  
13 reach a point where batches are actually outdating or  
14 batches on the shelves passing their use-by date and  
15 having to be disposed of?

16 A. Yes. I should perhaps just like to say that we have  
17 already seen the stock position at PFC, where we had  
18 figures for the end of each year, what the stock was.  
19 Unfortunately, we don't have similar stock reports for  
20 each of the regional transfusion centres. So this memo  
21 is really the information that we have to give us some  
22 sense of what stockholdings did exist at this time.

23 Q. Well, yes, Dr Perry does refer to other documents and  
24 trying to find the other documents to which he refers.  
25 Some of them are charts about where within PFC



1 particular material was, you know, what stage it was at.  
2 But there is also a document [\[SNB0073985\]](#), so the next  
3 in sequence, that I think goes with this. You see, that  
4 looks like his writing. Is that Dr Perry's writing?  
5 A. No, this is Mr Grant, who is our production manager. It  
6 is 1983.  
7 Q. Yes, November 1983. Could we go on to the next page,  
8 please? Yes. Still Mr Grant?  
9 A. Yes.  
10 Q. Did you have this page when you were --  
11 A. No.  
12 Q. All right. I'm not quite sure how we -- I know how we  
13 have it but we seem to have it following immediately  
14 after Dr Perry's memo.  
15 A. Presumably this is where he gets his 7 million.  
16 Q. Yes. Quite a big stock in Glasgow.  
17 A. I think that's in the memo. It talks about a large  
18 stock in Glasgow.  
19 Q. Yes. I don't think he gives any actual figures, though.  
20 That may be wrong.  
21 A. I think it's in the memo. It says 4.5 million, I think.  
22 Q. I think the 4.5 million maybe comes next. Can we go  
23 back to the memo? That's [\[SNB0073984\]](#). It is quite  
24 interesting. If we hold in our heads the Glasgow  
25 figure, which is 900,000 international units, and go

1 back to the memo at 3984, this is November 1983. I  
2 think that's a one-page memo, is it? So then if we go  
3 back to your paper --

4 THE CHAIRMAN: Could you just pause on it until I read it?

5 MS DUNLOP: Yes. Sorry, we need to go back to the memo.

6 [\[SNB0073984\]](#).

7 THE CHAIRMAN: Yes, he is presuming that the increase in  
8 stock levels reflects an excess of production over  
9 demand but, of course, present demand can mean a variety  
10 of things and if Glasgow, for example, were holding  
11 SNBTS material in stock but using commercial material at  
12 this time, one would get a divergence of this kind. It  
13 wouldn't just reflect in excess productive capacity.

14 A. That's true, yes.

15 THE CHAIRMAN: So it needs quite a bit of drilling into the  
16 material to find out precisely what the explanation was.

17 A. Yes.

18 THE CHAIRMAN: I really would like to see the histograms and  
19 so on, if I could, because there clearly are stories  
20 here that are not coming through in particular clarity.

21 I don't know how far we have to go, Ms Dunlop.

22 MS DUNLOP: I was only looking at this, sir, because  
23 Dr Foster had made the point about what was available in  
24 Glasgow in his paper and I looked for the surrounding  
25 documentation and I found the list in handwriting which

1 shows what the stock in Glasgow was in November 1983 and  
2 it's therefore remarkable, as Dr Foster goes on to say  
3 in his paper, in May 1984 a stock of 4.5 million  
4 international units is reported in Glasgow.

5 THE CHAIRMAN: Yes.

6 MS DUNLOP: That's really the point.

7 THE CHAIRMAN: Yes.

8 MS DUNLOP: I do not understand that. It's a very big rise.

9 THE CHAIRMAN: Well, it would suggest to me immediately that  
10 the reporting of data was not particularly reliable.  
11 That's the first thing one would consider because  
12 otherwise the explanation has to be pouring something  
13 like 3.6 million units from SNBTS into Glasgow during  
14 a relatively short period.

15 MS DUNLOP: Yes.

16 THE CHAIRMAN: And I think that might have been noticed.

17 MS DUNLOP: Well, indeed.

18 A. I think if you could go to the letter of Hopkins, it is  
19 possible it's somewhere where Hopkins does say that they  
20 have looked again and revised their figures.

21 MS DUNLOP: I don't have the number for that at the moment.  
22 We have looked at it already. It is a very memorable  
23 letter because of the terms in which it is expressed.

24 THE CHAIRMAN: This is sitting on a great big bundle.

25 MS DUNLOP: Yes. Certainly, I think so. Maybe we could

1 find it. It is a letter of 3 May 1984, please.

2 I should say, sir, the histograms are not very  
3 illuminating. For a start they are rather faint and  
4 they do just tend to show where in the facility various  
5 bits of stock are, rather than where in Scotland, which  
6 is perhaps more interesting for our purposes.

7 THE CHAIRMAN: I keep hoping for an easy way to communicate  
8 some of this information, Dr Foster, but I have been  
9 frustrated so far.

10 MS DUNLOP: Here we are.

11 THE CHAIRMAN: [\[SNB0074655\]](#).

12 MS DUNLOP: It's my mistake, sir. It's a different letter.  
13 It's the one that refers to using the A74 or the A1.  
14 Which is memorable too, but not as memorable as the  
15 letter about the Picts.

16 THE CHAIRMAN: Oh, yes, the A1 letter is earlier. The A1 is  
17 suggesting that it might just be put on a truck and sent  
18 down, yes. You don't want the December 1984 letter?

19 MS DUNLOP: Well, it was just that I think because Dr Foster  
20 has referred to this letter of Dr Hopkins, Dr Foster  
21 wanted to see it to see the reference to the  
22 4.5 million, and there it is and it's coming from Law.

23 A. I think there is another correspondence somewhere here  
24 where Dr Hopkins comes back and says, "We have looked  
25 again and we have actually discovered we have got more

1 Factor VIII". That might explain why some of the  
2 figures seem to change rapidly over a period of time,  
3 that he didn't have quite a good accurate figure of what  
4 was in the stock when he was communicating to Dr Perry.  
5 Dr Perry was dealing with this himself. I had nothing  
6 to do with it. So again, this is a topic you might want  
7 to discuss with him if you want to understand it better.

8 MS DUNLOP: Perhaps the only thing we can take from it  
9 Dr Foster is that around about this time there does seem  
10 to have been a large stock in the West of Scotland and  
11 I think that's about as far as we can get, possibly,  
12 which had risen greatly over a six-month period or  
13 possibly there have been errors at some point, and the  
14 rise is not as great as it might at first appear.

15 But you go on to narrate in your paper that the  
16 stock at this point was so high that 2.1 million  
17 international units were transferred to BPL. Thank you.

18 Then 1983/1984 to 1987/1988 which I don't  
19 particularly think we need to go into at the moment, and  
20 likewise the next section, 1988/1989 and 1989/1990 and  
21 so on. I wonder if we could just move forward to  
22 section 10, which deals with other countries. This is  
23 page 66.

24 Some description of what happened in England and  
25 Wales. Go on to the following page, please. Table 22

1 is your comparison between fresh-frozen plasma collected  
2 in Scotland and what was collected in England and Wales,  
3 and we can see quite a difference there. Then the  
4 paragraph at the bottom, you cover what you have already  
5 described, which is that decision to build at BPL rather  
6 than use PFC to fractionate English plasma.

7 Then on to the following page. You illustrate what  
8 happened in one part of England, the West Midlands  
9 Regional Health Authority. Is that because Dr Perry  
10 used to be there and had easy access to the material?

11 A. No, this is Professor Franklin's papers from the time he  
12 was a haemophilia doctor in Birmingham.

13 Q. You tell us what to take from the table. Maximum  
14 contribution from BPL to West Midlands of a little over  
15 50 per cent in 1983 and 1984, when in Scotland, SNBTS  
16 was supplying 94 per cent and over 99 per cent. A  
17 marked increase in the use of Factor VIII concentrate in  
18 1986 following the introduction of heat-treated  
19 products, and then a very high proportion of commercial  
20 Factor VIII in 1985, 1986 and 1987.

21 You say:

22 "Supply from BPL was at its lowest during 1985 to  
23 1987. Falling as low as 14 per cent and 15 per cent in  
24 the West Midlands region in 1985 and 1987 respectively."

25 On to the next page, please:

1           "Commercial Factor VIII concentrate that was safe  
2           from the transmission of Hepatitis C was not approved  
3           for use in the UK until December 1989."

4           So significantly beyond the time when the NHS in  
5           England and in Scotland had achieved that.

6           Other countries. Interesting to note the relative  
7           rates of blood donation. The most blood donations per  
8           thousand population appear to have been collected, at  
9           least in 1986, in Denmark, 79 blood donations for every  
10          thousand people; second Belgium, third Luxembourg,  
11          fourth France and fifth Scotland at 59 donations per  
12          thousand people.

13          I suppose everybody who worked for SNBTS was a blood  
14          donor, were they?

15   A. I don't know.

16   Q. Did you only give plasma or were you a blood donor as  
17          well?

18   A. I gave blood and plasma but then I stopped going because  
19          I had an illness and I didn't want to go back.

20   Q. I'm only thinking, because Professor Leikola told us  
21          when he was here that he gave blood, I suppose as much  
22          to test the systems as anything else.

23          Can we then move on to the next page, please? We  
24          revert to something that we saw this morning. If we  
25          look at the third paragraph, countries reporting being

1 self-sufficient according to WHO criteria, and this is  
2 reverting to the definition that we looked at this  
3 morning:

4 "The United Kingdom reported being self-sufficient  
5 according to its own definition."

6 We can see that definition again. We looked at that  
7 this morning. You say:

8 "According to the WHO definition, England and Wales  
9 never achieved self-sufficiency at any time."

10 Belgium and Switzerland both depended predominantly  
11 on freeze-dried cryoprecipitate, and you go on to tell  
12 us that continued use of unheated freeze-dried  
13 cryoprecipitate in Switzerland was associated with HIV  
14 infection in 67 people with haemophilia. The population  
15 of Switzerland being about, I gather, 7.7 million. In  
16 Denmark -- we can read that.

17 And conclusions --

18 THE CHAIRMAN: I want to understand the definition of  
19 self-sufficiency. Does it mean that if I plant one  
20 courgette plant this year, I can claim to be  
21 self-sufficient, provided I can get the other needs from  
22 Savacentre down the road.

23 A. That's what the UK Government definition seems to imply  
24 from 1990. As long as you prefer the Savacentre.

25 THE CHAIRMAN: Yes. And most times of the year that would



1 be so since my plant would either be immature or dead.

2 MS DUNLOP: Most importantly for the purposes of the  
3 Inquiry, Dr Foster, the two paragraphs in your  
4 conclusions that begin with an "if", firstly:

5 "If cryoprecipitate is accepted as having been  
6 suitable for the treatment of Haemophilia A when there  
7 was a shortfall of Factor VIII concentrate, sufficient  
8 Factor VIII was supplied by the SNBTS to provide  
9 treatment at the average UK level throughout the period  
10 from 1975/1976 to 1989/1990, except for 1982/1983, but  
11 if cryoprecipitate is considered to have been  
12 unsuitable, then you say:

13 "Supply from the SNBTS did not fully match the level  
14 used in the UK until 1983/1984."

15 THE CHAIRMAN: Ms Dunlop, I think it's time for a short  
16 break.

17 MS DUNLOP: Yes, absolutely. I think we don't really need  
18 to take any more from this paper, sir. We have reached  
19 the conclusion. Perhaps we can just look at it briefly  
20 when we resume and then go back to the statement.

21 THE CHAIRMAN: What format does your data stand in? Is it  
22 Word or by any chance could it be put into a different  
23 format and converted into tables and diagrams and so on?

24 A. It's in Word at the moment and I can't claim to be adept  
25 at formatting anything, so I would rather somebody else

1 did that but I don't see why not.

2 THE CHAIRMAN: If you can make it available, I think we can  
3 find the resources to manage it.

4 (3.21 pm)

5 (Short break)

6 (3.40 pm)

7 THE CHAIRMAN: Dr Foster, could we look at table 16, please,  
8 for a moment?

9 In that you have set out the Factor VIII production.

10 PROFESSOR JAMES: 1182.

11 THE CHAIRMAN: Sorry, thank you. At SNBTS from 1979 to  
12 1985, and these are figures, as I understand it, that  
13 are available to you within SNBTS.

14 A. That's correct, yes.

15 THE CHAIRMAN: If we look at the second column, we have the  
16 amount of SNBTS Factor VIII used clinically year by year  
17 and we compare the two, and making allowance for 1980,  
18 when the use exceeded production by a small margin, it  
19 appears that SNBTS production was about 9.5 million  
20 units more than use over that period. Where did it go?

21 A. Well, 2 million units went to England. 2 million units  
22 went to England.

23 Q. To England, right?

24 A. Yes. Then when we introduced heat treatment, there was  
25 a yield penalty because we heated the stock of material

1           we had.

2   THE CHAIRMAN: That I remember. You drew it all back in.

3   A. That's correct. Then when we made a transition to the

4           product that was heated at 80 degrees, we actually

5           stopped production for about six months or longer before

6           we introduced that product and the stocks that were left

7           over from this allowed us to do that.

8   THE CHAIRMAN: So they were all recycled, were they?

9   A. They were all used one way or another, yes.

10   THE CHAIRMAN: I can understand that up to a point. The

11           difficulty was that heat treatment was 1984 onwards and

12           predominantly it was the first half of 1985 that the

13           stocks were drawn back for reprocessing, as I understand

14           it.

15   A. That's correct, yes.

16   THE CHAIRMAN: So that might deal with the very end of the

17           history, as it were, but quite a lot of that surplus has

18           built up in the middle section of this table, if one

19           looks at it. We have got in 1981 an excess of

20           2.1 million units of production; 1982, an excess of

21           nearly 2 million units of production; 1983, an excess of

22           over 4 million units of production; and I rather

23           recollect that again it was in 1984 that the major

24           export, if I can call it an export, of material to

25           England took place.

1           If that impression is correct, there is still a very  
2           considerable excess of production over use in the middle  
3           part of this table and it does still raise the question:  
4           where was it? Where did it go?

5    A. We would have to try and go back and look at that in  
6           more detail, if that is what you would like us to do,  
7           but my feeling is that when we heat-treated the  
8           Factor VIII, we would have a yield penalty of about  
9           20 per cent. Then we increased the heat treatment, so  
10          we had an even higher yield penalty, and it's  
11          conceivable that there were some batches that didn't  
12          withstand heat treatment that didn't get used, and then  
13          we had a period where we stopped production for about  
14          six months or so while we developed the heat-treated  
15          product at 80 degrees.

16          So all of that taken together I had assumed would  
17          accommodate that but I can't say for sure that was the  
18          case.

19    THE CHAIRMAN: I would be happy if that were the explanation  
20          but my difficulty is timing because I think it  
21          was November 1984 that the experiment with heat treating  
22          material was carried out, following the information  
23          obtained at the conference on the continent, and you  
24          discovered in PFC that you could heat treat the  
25          intermediate Factor VIII without significant loss of

1 activity and in the event that met the criteria for AIDS  
2 inactivation. Then there was the development, largely  
3 in England, of the extra heat-treated process, the dry  
4 method, that was adopted in Scotland. But that was well  
5 into 1986, was it not?

6 A. That's correct, yes.

7 THE CHAIRMAN: So that can't explain this build-up of data.

8 A. My -- and this is very, very rough -- memory is that we  
9 had about 12 months' supply of Factor VIII that we  
10 called from stock and we heated at the end of 1984/early  
11 1985 and, because of the yield penalty and possibly  
12 increased usage, I'm not sure, that lasted us almost  
13 through 1985, before we then moved on to the next stage,  
14 which was the product heated for 24 hours at 68.

15 THE CHAIRMAN: Could you look at it again? Because my  
16 current impression is that these factors you point to  
17 would be a very good explanation of what happened in  
18 1985 and 1986 and 1987, but it leaves rather a gap in  
19 one's understanding of what appears to be significant  
20 excess production as against use in the middle parts of  
21 your table. If there is a good explanation for it,  
22 I would be delighted to hear it.

23 A. Yes. The other point I should perhaps mention, that has  
24 just occurred to me, is that we did have a three months'  
25 shutdown at the end of 1984, when we stopped production

1           altogether. So again, as we talked about earlier, there  
2           were periods when we stopped production to make changes  
3           to PFC, and there was quite a significant period of  
4           shutdown at the end of 1984.

5   THE CHAIRMAN: Just as there had been in 1983?

6   A. Exactly.

7   THE CHAIRMAN: But in 1983 you were still able to produce  
8           more overall than the demand for that year.

9   A. Yes.

10   THE CHAIRMAN: So at the moment I have got a concern and it  
11           is that there may have been an unproductive production,  
12           if I can put it that way, in the sense that PFC was  
13           maintaining a high level of production but the  
14           Factor VIII product was not finding its way into  
15           patients. That could be for a number of reasons:  
16           product selection could have been one of them by the  
17           clinicians; another could have been the failure to use  
18           the product before it became dated; all sorts of  
19           theoretical possibilities that seem to emerge out of the  
20           raw data, and I would really like that to be looked at.

21   A. Yes. I have to say I'm not aware there was ever any  
22           surplus Factor VIII that never got used and that was  
23           disposed of. That's not something I have ever heard of  
24           but we could look into that.

25   THE CHAIRMAN: I would like an answer to it since one can't

1           just look at the raw data here and immediately assume  
2           that there wasn't a problem. You might, of course, not  
3           have had any returns since -- as you know, I have got  
4           some concerns about the data that was returned,  
5           centrally, before Dr Stewart came along.

6           Now, Ms Dunlop.

7 MS DUNLOP: Yes, thank you, sir. I suppose the other  
8           possibility, Dr Foster, is that the UKHCDO data might be  
9           incomplete, their figures for how much was used.

10 A. Yes, I have taken these figures from your preliminary  
11          report, so it goes back to those data.

12 Q. Yes, and as we understand Dr Hay's evidence, they ask  
13          for usage to be reported to them but I suppose it's  
14          conceivable that there could have been some usage that,  
15          for whatever reason, someone omitted to report to  
16          UKHCDO. That would be another contributing factor.

17 THE CHAIRMAN: Yes, that just leads us eventually to  
18          conclude that the data is so unreliable that no one can  
19          form any views on the basis of it at all. I'm sure  
20          Mr Anderson would be delighted to have a finding like  
21          that.

22 MS DUNLOP: Dr Foster, we have your conclusions. Just so  
23          that we understand them, if we look at page 71 again, it  
24          was the second paragraph that begins "if", where you say  
25          that if cryoprecipitate was considered to be unsuitable,

1 supply from the SNBTS did not fully match the level used  
2 in the UK until 1983/1984. Despite this apparent  
3 shortfall in supply of Factor VIII concentrate,  
4 production of Factor VIII concentrate at PFC exceeded  
5 that amount of concentrate used throughout during 1979  
6 to 1985, except for 1980, when the amount use doubled,  
7 I think that is, in one year. That is table 16, is it?

8 A. Yes.

9 Q. Just so that we understand that. We can read the rest  
10 for ourselves. We know that most commercial Factor VIII  
11 purchased in Scotland in the early 1980s was obtained by  
12 haemophilia centres in Glasgow. It was comparable in  
13 quantity to the unused stock of SNBTS Factor VIII  
14 concentrate that had accumulated at the Glasgow  
15 regional transfusion centre?

16 THE CHAIRMAN: Is that 4.5 million units or what?

17 MS DUNLOP: Well, if you added up the commercial purchases  
18 from Glasgow in the early 1980s, they would be a lot  
19 less than the 4.5 million in fact, but the 4.5 million  
20 is 1984 and the commercial purchases are around about  
21 0.9 and 0.8, I think, Dr Foster, if I recollect  
22 correctly, page 62 --

23 THE CHAIRMAN: Does that include The Royal, Ms Dunlop?

24 MS DUNLOP: I don't know, sir, this is Dr Foster's table.  
25 Commercial Factor VIII concentrate, purchase of



1 commercial Factor VIII concentrate by region. I imagine  
2 it would be both the Royal and Yorkhill.

3 PROFESSOR JAMES: Table 16 specifically excludes Koate from  
4 the Royal.

5 MS DUNLOP: Well, this is based on SNBTS information about  
6 purchases, sir, so it is actually a different source of  
7 information altogether. Table 20 is based on  
8 information held by SNBTS prior to the publication of  
9 the preliminary report. So the total purchases in  
10 Glasgow from 1978 to 1983, as it were, 3.96 -- I think  
11 that's the comparison you are making, is it, Dr Foster?

12 A. Yes, I may really have made a mistake here and it's  
13 possible that I should have said "use" rather than  
14 "purchase" and was referring to table 16. Presumably it  
15 was purchased before it was used. So in that sense it  
16 was purchased, but it is not in our data of purchases.

17 Q. Yes.

18 THE CHAIRMAN: Dr Foster, it should be no surprise that  
19 I don't expect any of these tables or any sources of  
20 information always to be right the first time round. If  
21 you want to revise any of it --

22 A. I'm not sure I do.

23 THE CHAIRMAN: If you just let us know.

24 A. I'm meaning table 16 when I say "purchase", assuming  
25 that the material wasn't provided free of charge before

1           it was clinically used, then it was purchased.

2   THE CHAIRMAN: I repeat, I'm perfectly content for you to  
3           correct anything that you think needs to be corrected.

4   A. Thank you.

5   THE CHAIRMAN: But not to speculate. I wouldn't want you to  
6           change something just on an off chance.

7   A. Thank you.

8   MS DUNLOP: It was the last sentence on page 71, Dr Foster:

9           "Most commercial Factor VIII purchased in Scotland  
10          in the early 1980s was obtained by haemophilia centres  
11          in Glasgow."

12          Is that not table 20? It certainly seems to be  
13          vouched by table 20 on page 62.

14   A. Yes, okay, I'll defer to that. Yes, table 20.

15   Q. No, you tell me. It's just that table 20 seems to make  
16          that point. Glasgow is quite a long way in front. Is  
17          that right?

18   A. Yes, I would accept it's table 20, yes.

19   Q. Right. Then we have looked at such information as we  
20          seem to have about what was sitting in Glasgow  
21          in November 1983 and May 1984 but with the health  
22          warning that that's rather hard to understand. Then you  
23          say:

24          "Supplies were sufficiently strong thereafter to  
25          avoid commercial Factor VIII concentrate being purchased

1 in Scotland until 1988 to 1989."

2 You have given us six bullets to show how SNBTS  
3 achieved what they achieved even without plasmapheresis.

4 THE CHAIRMAN: Just contemplating the range of problems that  
5 there might be, Ms Dunlop. But, of course, where we  
6 have data with different reference periods, calendar  
7 years on the one hand, financial years on the other and  
8 data for purchases at some level and data for use at  
9 others, and really at the moment irreconcilable stock  
10 figures, it all becomes extremely difficult to  
11 rationalise and present a comprehensive picture,  
12 Dr Foster.

13 A. I quite accept that and I obviously have had difficulty  
14 putting those figures together in the first place  
15 because -- it is a long time ago and a lot of the raw  
16 data are not available.

17 THE CHAIRMAN: I'm sure I'm extremely grateful for the work  
18 you have done because I do know how difficult it has  
19 been for us to try to put figures together, but let's  
20 see if we can get even better in time.

21 MS DUNLOP: Certainly, sir, some bits of it -- and I accept  
22 at a high level -- some bits fit with the narrative that  
23 we have heard from other witnesses about the patterns of  
24 usage in different parts of the country.

25 THE CHAIRMAN: I'm not absolutely sure. If we look at table

1           20 and take a per capita approach into account,  
2           Edinburgh's use of commercial products in 1980/1981  
3           onwards, doesn't look as small, as it were, given that  
4           Glasgow's population is several times that of Edinburgh;  
5           lots of factors that might have to come into the  
6           assessment of the significance of the data.

7           It certainly doesn't look as if there was  
8           a predominant use of PFC to the exclusion of commercial  
9           products in Edinburgh.

10   MS DUNLOP: I suppose, sir, the relevance for the Inquiry  
11           would be in looking at Professor Ludlam's data about how  
12           many patients were infected by commercial material,  
13           which, if my recollection is correct, is, one. So as  
14           between Glasgow and Edinburgh, we are looking at a much  
15           higher rate of infection from commercial product in  
16           Glasgow than in Edinburgh.

17   THE CHAIRMAN: I know, which may be explained on the  
18           specifics of the commercial product, I don't know.

19   MS DUNLOP: Yes. Sir, we have finished Dr Foster's paper  
20           and I obviously have to go back to his statement and  
21           cover some other matters that he raises there, but  
22           I think it would be better done tomorrow when we might  
23           be fresher.

24   THE CHAIRMAN: You might be right.

25   MS DUNLOP: If I can put it like that.

1 THE CHAIRMAN: Ms Dunlop always knows when I'm becoming less  
2 than fresh.

3 MS DUNLOP: I think I was referring to myself, sir.

4 THE CHAIRMAN: I take it as a general comment that probably  
5 applies to everyone.

6 I do like figures. I'm an accountant after all, but  
7 yes, they get a bit much after a time.

8 Tomorrow morning.

9 (3.59 pm)

10 (The Inquiry adjourned until 9.30 am the following day)

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13 DR PETER FOSTER (sworn) .....1

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15 Questions by MS DUNLOP .....1

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